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INTRAOPERATIVE ASEPTIC PRACTICES AND SURGICAL SITE INFECTIONS IN BREAST SURGERY

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ACADEMIC DISSERTATION

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ABSTRACT

Background and aims. Operating theatre (OT) personnel implement intraoperative aseptic practices (AP) to control and prevent surgical site infection (SSI). AP is considered important in both infection control (IC) and prevention (IP), despite the challenges of investigating the causality between APs and SSIs. This study introduces a project regarding co-creating intraoperative APs in the OTs of one university hospital, with another hospital functioning as a comparison setting. Objectives for this study were: 1) to investigate the acceptance of and adherence to APs among OT personnel before and after the co-creation of the evidence-based intraoperative APs and during the follow-up study; 2) to introduce assessment tools for the intraoperative APs for further development and improvement; 3) to explore performance of AP-related clinical situations; and 4) to define risk factors for SSIs in breast operations.

Methods. Outcomes of the project were measured as changes in the acceptance of and self-reported adherence to the AP recommendations, and as SSIs in breast surgery. A follow-up study was completed 12 years after the co-creation of the AP recommendations. First, the acceptance of and adherence to the AP recommendations were surveyed among OT personnel before (N=211) and after (N=234) the co-creation of the recommended APs. Twelve years after the co-creation, a follow-up survey was completed only for nurses both in the study and comparison hospital (N=242). An initial literature based intraoperative AP model created to facilitate the AP recommendation co-creation process. Descriptive statistics and summation variables were computed for assessing the AP recommendation acceptance and adherence. Second, using the variables of the aforementioned survey, separate AP assessment tools were created for circulating and scrub nurses. The initial AP model served as a structure for the tools. Clinically relevant assessment criteria were selected to achieve a high internal consistency for the scales. Third, qualitative research was completed in the study hospital. Video recordings of 31 operations served as stimulated recalls during interviews of 31 circulating nurses. The APs were observed and feedback discussions completed at the end of interviews using a criteria-based observation tool. Fourth, all breast-operation-related patient documents (N=1042) and SSI statistics from infection register in the two hospitals were reviewed before and after the co-creation of the AP recommendations. After removing contaminated and infected operations descriptive statistics and logistic regression analyses computed to define the SSI risk factors for all breast operations (N=982), lumpectomies (n=700) and mastectomies (n=282).

Results. Statistically significant differences in recommendation acceptance were found between professions and genders before and after the recommendation co-creation measured according to establishment, maintenance and disestablishment of the sterile field. Between study and coparison hospitals the differences were significant exept not during the disestablishment of the sterile field before co-creation. In self-reported prevention of handborne contamination, differences were found between

hospitals, professions and those 52 respondents participated in both measurements. In preventing airborne contamination, differences were found between hospitals and among the 52 respondents. In preventing bloodborne contamination, differences were found between professions, genders and the 52 respondents. The self-reported adherence to preventing bloodborne infections was found to be higher among those respondents with no needlestick injuries from used needles than those reporting a needlestick.

After the follow-up survey, a 20-item tool with good scale reliability was constructed for assessing the AP of circulating nurses. The three phases of AP– establishment, maintenance, and disestablishment of the sterile field – structured the tool. In testing the tool, differences were found in AP recommendation acceptance according to education and working experience. Three tools were constructed for scrub nurses. One was for preparing to work, one for working in the sterile field and one for reporting adherence to AP recommendations during maintenance of the sterile field. No differences were found in the acceptance and self-reported AP adherence by demographics among day surgery and OT nurses.

The stimulated recall interviews (N=31) of the circulating nurses in the study hospital found variation in adherence to recommended intraoperative APs. The circulating nurses expressed working experience-, time- and equipment-related stress in implementing APs. Also working with demanding persons in OT team, challenges with patients, working morals and power-related stress reported regarding implementing the intraoperative AP recommendations. The OT nurses managed the stress by both active and withdrawal behaviour. Reactions were individual and situation specific.

No improvement was found in postoperative SSI rates after the co-creation of AP recommendations in the study hospital. A multivariate logistic regression model for all the breast operations (N=982), lumpectomies (n=700) and mastectomies (n=282) was built to explain the risks for postoperative infections (6.7%). In all operations, a contaminated or dirty wound, high American Society of Anaesthesiologists' score, high patient body mass index, use of surgical drains, and re-operation predicted increased SSI risk. High patient body mass index and use of surgical drains predicted an increased risk in lumpectomies. In mastectomies, the statistically significant predictor was re-operation.

Conclusions. The varying acceptance of and adherence to the intraoperative AP recommendations requires improvement. Stress due to the challenges in implementing the AP recommendations is avoidable by co-created evidence-based APs. The SSI risks in breast operations may be managed by considering the use of antimicrobial prophylaxis in re-operations and obese patients. The assessment of intraoperative IP is possible to improve by including the baseline AP model and relevant criteria in the documentation. More carefully planned and implemented projects are necessary for improving the evidence-based recommendations for intraoperative AP to secure the safety of the surgical patients, personnel and environment among anaesthesia personnel also. The expertise of the personnel is important to develop through participative and strategic training and structured follow-up reporting.

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CONTENTS

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications:

I Aholaakko T.-K. 2011. Reducing surgical nurses' aseptic practice–related stress. Journal of Clinical Nursing 20 (23-24), 3339–3350.

II Aholaakko, T.-K., Metsälä, E., Sihvonen, M. & Lyytikäinen, O. 2013. Risk factors for surgical site infection in breast surgery. Journal of Clinical Nursing 22, 948-957.

III Aholaakko, T.-K. & Metsälä. 2015. Intraoperative aseptic practice recommendations for circulating operating theatre nurses. British Journal of Nursing 24 (13), 670-678.

The publications are referred to in the text by their roman numerals.

ABBREVIATIONS

AB	Aseptic Behaviour
AMP	Antimicrobial Prophylaxis
AORN	Association of Operating Room Nurses / Association of periOperative Registered Nurses
AP	Aseptic Practice
ASA	American Society of Anesthesiologists
AT	Aseptic Technique
BMI	Body Mass Index
CDC	Centers for Disease and Control and Prevention (US)
CFUs /m^3	Colony-forming units per cubic meter
DM	Diabetes Mellitus
ECDC	European Centers for Disease and Control and Prevention
EU	European Union
HAI	Hospital-acquired / Healthcare-associated Infections
HIS	Hospital Infection Society (UK)
IC	Infection Control
IP	Infection Prevention
NHSN	National Healthcare Safety Network
NNIS	National Nosocomial Infection Surveillance System
OT	Operating Theatre
SENIC	Study of Nosocomial Infection Control
SP	Standard Precautions
SSI	Surgical Site Infection
UP	Universal Precautions
US	The United States
WHO	World Health Organization

1 INTRODUCTION

During the last 150 years, the development of medicine and institutionalised care caused undesired consequences for societies and individuals. The recognition that for surgical patients it was safer to recover in a stable than in public hospitals started the modern development of safer caring environments and practices (Lister 1870 a&b; Cohen 1999). Two of medicine's ten greatest discoveries are related to surgical practice: Anthony Leeuwenhoek's detections of bacteria and Alexander Fleming's of antibiotics (Friedman & Friedland 1998). Both are still currently relevant regarding research and clinical development. They also both cause problems when serving as a master, not as a servant.

Nurse pioneers, Rufaida al-Asalmiyh in the Islamic Wars and Florence Nightingale in the Crimean War, both influenced the field by improving environmental hygiene and developed practices facilitating the recovery of wounded soldiers (Meleis 1991; Tumulty 2001; Miller-Rosser et al. 2006). Present-day intraoperative aseptic practices (AP) comprise the cornerstones of perioperative infection prevention (IP) and infection control (IC) conducted to reduce surgical site infections (SSI) (Sub-committee on aseptic methods in operating theatres of their committee on hospital infection 1968; Mangram et al. 1999; AORN 2013; Storr et al. 2017).

SSIs comprise one of the most frequent groups of hospital acquired infections (HAI) in acute care hospitals. Pneumonias, SSIs, urinary tract infections, bloodstream and gastrointestinal infections cause human suffering, unnecessary deaths and increased fiscal burden (EU Council 2009; Allegranzi et al. 2011; Magill et al. 2015; Badia et al. 2017). In 2013-2014, in the European Union (EU), the annual prevalence of HAIs was over four million. SSIs and pneumonia are the most common HAIs. The SSI rates varied between 0.6 and 9.5%, measured in 967,191 surgical procedures. In 59 Finnish hospitals, the prevalence of HAIs was 7.4%, and the proportion of SSIs was 24% in 2011 (Kärki & Lyytikäinen 2013). In the United States (US), the estimated number of SSIs was 157,500 in 2011 (Magill et al. 2015). According to the World Health Organization (WHO) (2017), SSIs are the leading type of infection in developing countries, affecting up to one-third of operated patients, nine times more than in developed countries.

Of HAIs, 20 to 30% are estimated to be preventable by intensive hygiene and control programmes (Haley et al. 1985b; ECDC 2017; Storr et al. 2017). The Centers for Disease Control and Prevention in the US (CDC 2016a) and in Europe (ECDC 2016 & 2017) reported a steady decrease in SSI rates.

No systematically developed guidelines exist to all-inclusively cover the intraoperative APs. Some of the traditional intraoperative aseptic techniques (AT) introduced by Lister (1870 a&b) and Brewer (1915) are still in clinical use. They can be called rituals if performed according to custom, without

understanding the reasons why and not having a sufficient evidence-base (Woodhead et al. 2002).

Evidence-based intraoperative AP guidelines exist for selected procedurals (Rowley & Clare 2009; Rowley et al. 2010; Alexander et al. 2011; SIGN 2014) and for surgical safety (American College of Surgeons 2007; WHO 2009; The Royal College of Nursing 2013). Globally, the most referred to AP recommendations are the Association of periOperative Registered Nurses (AORN) Recommended Practices. They are not based on a holistic conceptual model of intraoperative AP and the used evidence is not consistent, but they do focus on the AP of all surgical team members. They do not completely meet the requirement for evidence-based IC and IP guidelines (Francke et al. 2008), but the progress in using evidence is visible.

This study introduces a long-time effort to co-create and update intraoperative APs ensuring patient, occupational and environmental safety in the framework of an initial model for intraoperative AP between hospital personnel and researcher. The AP-model and scales were co-created and tested in authentic intraoperative contexts. In enhancing intraoperative quality of care, the participation of all medical and nursing practitioners was aimed for, but not realised. The co-creation with the clinical professionals and the researcher was a strategic choice (Im & Meleis 1999). All participants accepted a standard of using and producing knowledge that was as valid, reliable and relevant as possible during this project. The external evaluation of used and produced knowledge was performed by presenting the initial and final results at conferences (Liljeblad 2001; 2003; 2005; 2006a & b; Liljeblad & Sihvonen 2005a &b; Aholaakko 2009), in professional journals (Liljeblad et al. 2002) and with nursing students in educational settings (Aholaakko 2011; Laitinen et al. 2015). The intraoperative APs were considered worth developing and investigating as sustainable, cost-effective and evidence-based approaches to keeping up surgical safety in the future.

In this study, the terms perioperative and operating theatre (OT) nurses, surgery and surgical nurses are considered synonyms. The scrubbed personnel works with surgical hand scrub and relevant sterile protective barriers in assistance of circulating nurse. This study focuses on developing APs in clean and clean-contaminated operations from scrubbed personnel and circulating nurses' viewpoints excluding APs in anesthesia care. The surgical patient may be a carrier of microbes with resistance or limited activity against antimicrobial medication, or the infectious disease of the patient may be in an active phase. The isolation measures required in these situations are not included as the focus of this study. The requirements for APs in reducing microbial contamination of invasive operation sites were related to patient and operation characteristics. The breast operations were selected as a focus group during the data collection, aiming to improve the validity and reliability of the results. This thesis consists of this summary and three original papers (I – III) published in peer-reviewed journals. The summary part provides a theoretical background for the original papers.

2 REVIEW OF THE LITERATURE

The safety and quality of healthcare and their measurements are fundamental elements of present-day healthcare delivery. The performance of evidence-based surgical care includes the implementation of both pre-operative and intraoperative infection prevention (IP) and control (IC) measures. Aseptic practices (APs) are performed as part of IC and IP. APs are focused on safeguarding the surgical patient from surgical site infections (SSI) and the surgical personnel from occupational infections and maintaining the environmental safety in surgical practice settings.

2.1 SURVEILLANCE OF SURGICAL SITE INFECTIONS

SSI surveillance is part of a wider infection surveillance system associated with healthcare services (Olson & Lee 1990; Lee et al. 2007). In addition to HAI, community acquired infections, and infections detected within 48 hours of hospital admission in patients that had previous contact with healthcare service within the past year, are the contemporary focus of IP and IC (Cardoso et al. 2014).

According to current evidence, the microbes causing SSIs can originate from the patient (Fleishman et al. 1996), perioperative personnel (Hambraeus 1998; Kolmos et al. 1998; Tammelin et al. 2001), equipment (Flaherty & Wick 1993; Gautier et al. 1993; Campbell et al. 1993; Dancer et al. 2012) or from the surgical environment (Friberg & Friberg 2005). Most of postoperative SSIs reported are endogenously acquired. In addition to patient-related risk factors, SSIs are associated with invasive procedures, longer pre- and postoperative hospital stays, additional surgical procedures and treatment in intensive care units (Scott et al. 2001; Perencevich et al. 2003; Witt et al. 2003; Geubbels, Grobbe et al. 2006; Geubbels, Nagelkerke et al. 2006; Olsen et al. 2008 & 2015, EU Council 2009; WHO 2011; Zingg et al. 2015; CDC 2016a; ECDC 2016). The patient-related infection risks and the emergency of the operation are reported as being more important than the environmental microbial load in operating theatre (OT).

Globally, some reports exist of burdens due to SSIs. SSIs increase healthcare costs and losses due to the increased length of the hospital stays, 30-day readmission rate, and reduced profits for patients with an SSI compared with patients without an SSI (Perencevich et al. 2003; Graves 2004; Shephard et al. 2013; Badia et al. 2017). A US study reported that 67% (816 of 1,223) of the patients with a complex postoperative SSI required hospital readmission (Ming et al. 2012). Rioux, Grandbastien and Astagneau (2006) reported that 21% of SSI patients in France required a second surgical procedure. In Finland, Kanerva and colleagues estimated that annually

48,000 hospitalisations lead to at least one HAI and that 1,500 patients die with an HAI. Based on international estimations, the annual burden of HAIs in Finnish acute care hospitals was 195-492 million Euros. (Kanerva et al. 2009.) The Finnish SSI-related financial burdens, reported by Hyrylä and Sintonen in 1994, were 1.2 million Finnish Marks (~200 000 Euros). Of those extra costs, 85% were paid by the communities and 15% by the patients. Employers carried 30% of the production losses and replacements.

In Finland, national surveillance of SSIs was voluntary until 2017. Also, the Finnish Hospital Discharge Register (FHDR), HILMO, database is used in reporting surgery-related patient information, diagnoses and treatments. According to Sund (2012), more than 95% of Finnish hospital discharges were identified from the FHDR with a positive predictive value for common diagnoses between 75 and 99%. The most obvious limitations for the validity of the FHDR data were the poor recording of subsidiary diagnoses, secondary operations and other rarely used items. Kanerva et al. (2009) found variations in HAI reporting according to the severity of the infection. Of the organ SSIs, 54% were reported in the FHDR.

Inconsistancy in the definition of HAIs (Larson et al. 1991; Crowe & Cooke 1998; Wilson et al. 2004; Allegranzi et al. 2011; Kärki & Lyytikäinen 2013), underreporting of SSIs (Poulsen & Meyer 1996; Reilly et al. 2006), and variations in follow-up criteria and times (Yokoe et al. 1998; McKibben et al. 2005; Rioux et al. 2006) biased the comparison of SSI surveillance results. Among others, Moro's group (2005) discussed the intensity of post-discharge surveillance as partly explaining the observed differences in SSI rates. The consistent use of a single definition can show changes in SSI rates at a single centere over time, but differences in interpretation can bias comparison between different centeres (Wilson et al. 2004; Kanerva et al. 2009; Kärki & Lyytikäinen 2013).

2.1.1 DEFINITION OF SURGICAL SITE INFECTIONS

SSIs are traditionally classified as HAIs according to their place of acquisition. The increased number of outpatient surgery and mandatory infection surveillance after selected operations (e.g., orthopaedic surgery in the United Kingdom) created requirements to update the definitions and surveillance procedures. (Reilly et al. 2006; Ming et al. 2012; Cardoso et al. 2014; Macefield et al. 2017).

According to Wilson et al. (2004), the four common definitions for SSI used during the recent decades are the CDC 1992 definition, the National Nosocomial Infections Surveillance (NNIS) modification of the CDC definition (Table 1), the presence of pus, and the ASEPSIS scoring. A quantitative scoring method, ASEPSIS, provides a numerical score (0–30) related to the severity of wound infection. Scores between 10 and 20 indicate SSI (Sherlaw-Johnson et al. 2007). ASEPSIS scoring used criteria based on wound appearances (e.g.,

number of wounds) and the clinical consequences of infection, but it is not well validated outside of cardio-thoracic surgery (Siah & Childs 2011).

Table 1 *Definitions of surgical site infections according to Centers of Disease Control and Prevention (modified from Mangram, Horan, Pearson, Silver and Jarvis 1999).*

Criteria for defining a surgical site infection (SSI)
Superficial Incisional SSI:
Infection occurring within 30 days postoperatively involving only skin or subcutaneous tissue of the incision and at least one of the following: 1. Purulent drainage (with or without laboratory confirmation) from the superficial incision. 2. Organisms isolated from (an aseptically obtained culture of fluid or tissue) the superficial incision. 3. At least one of the following signs / symptoms of infection: pain or tenderness; localized swelling; redness, or heat; and superficial incision is deliberately opened by surgeon, unless incision is culture-negative. 4. Diagnosis of superficial incisional SSI defined by the surgeon or attending physician.
Deep Incisional SSI:
Infection occurring within 30 days postoperatively (no implant placed) or within 1 year (implant placed) relating to the operation and involving deep soft tissues (e.g. fascial/muscle layers) of the incision at least one of the following: 1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site. 2. A deep incision is spontaneously dehisced or deliberately opened by a surgeon and patient has at least one of the following signs or symptoms: body temperature >38ºC; localized pain or tenderness (unless site is culture-negative). 3. An abscess (or other evidence of infection) involving the deep incision found on direct examination; during reoperation; or by histopathologic or radiologic examination. 4. Diagnosis of a deep incisional SSI defined by a surgeon or attending physician.
Organ/Space SSI
Infection occurring within 30 days postoperatively (no implant placed) or within 1 year (implant placed) relating to the operation and involving any part of the anatomy (e.g., organs or spaces), other than the incision opened or manipulated during an operation and at least one of the following: 1. Purulent drainage from a drain placed through a stab wound into the organ/space. 2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space. 3. An abscess or other evidence of infection involving the organ/space found on direct examination; during reoperation; or by histopathologic or radiologic examination. 4. Diagnosis of an organ/space SSI defined by a surgeon or attending physician.

2.1.2 DEFINITION OF SURGICAL SITE INFECTION RISKS

The original CDC risk index for wound infections was developed in the Study of Nosocomial Infection Control (SENIC project) in the 1980's. It consisted of four criteria (operation involving the abdomen, duration of operation more than two hours, operation classified as contaminated or dirty, and patient having three or more diagnoses during discharge). The use of the wound contamination classification was complex. Disagreement existed regarding whether the breaks in technique (surgical / aseptic) should be included in the classification. The follow-up times in the updated NNIS risk index were 30 days for superficial and deep or organ / space infections, and one year

for orthopaedic operations implementing prosthesis (Haley et al. 1985a; Haley 1991).

After the SENIC project, the core of wound infection (later SSI) risk estimations were built on three NNIS indicators: 1) classified risk for patient's anaesthesia according to the American Society of Anesthesiologists' (ASA) definition, 2) classification for wound contamination, and 3) long duration of operation (Haley et al. 1985a; Haley 1991; Horan et al. 1992; Horan & Emori 1997; de Blacam et al. 2012). The patients' SSI risk index is categorised from zero to three.

The National Healthcare Safety Network (NHSN) risk index (based on the presence of three major risk index factors: the duration of the operation; wound contamination class; and the ASA physical status classification), was used to assign all surgical patients to one of the four categories (0 to 3) (Mangram et al. 1999; NNIS 2004; ECDC 2016).

The updated NNIS risk index (Table 2) is in use in Europe and Finland. It is a combination of patient and procedure characteristics consisting of three factors. The ASA score of 3 or more measures the patient's health status, the wound class 3 or 4 equivalents the contaminated or infected wound status and the operation time (T) determines the operations as short or long by their duration (Culver et al. 1991; Horan et al. 1992; Horan & Emori 1997*;* Gaynes et al. 2001).

The duration of the operation is defined as the time between the skin incision and completion of the skin closure. According to Leong, Wilson and Charlett (2006), an extended duration of surgery may serve as a marker for the complexity of the individual case, some aspect of the surgical technique, prolonged exposure to microorganisms in the operating environment, and diminishes the efficacy of microbial prophylaxis. In addition to planned actions, the measured real operation time includes all the delays interfering in the continuum of the operation. In some countries, the local T times are suggested to replace the NNIS system T time. The use of local T times complicates the comparison between local and published results (Prospero et al. 2007).

The contemporary consensus stresses that SSI rates vary according to operation types (Prospero et al. 2006 & 2007; Reilly et al. 2006; Rioux et al. 2006; Saeed et al. 2015). The usefulness of tailoring the SSI risk indices to specific operation types has long been a focus of discussion (Haley 1991; Prospero et al. 2006; Reilly et al. 2006; Rioux et al. 2006; Davis et al. 2013; Saeed et al. 2015; Olsen et al. 2015). In particular, procedure-related factors were recommended to be measured if large variation in SSI rates between hospitals existed (Geubbels, Grobbe et al. 2006; Geubbels, Nagelkerke et al. 2006). In the US, the NHSN risk index is determined and tested regarding measuring variations in SSI rates within 40 categories for surgical procedures. Focusing on mandatory infection reporting and surveillance on the complex SSIs diagnosed in inpatient settings is suggested. This was reasoned by varying levels of hospitals. (Saeed et al. 2015.)

Table 2 *National Nosocomial Infections Surveillance System (NNIS) updated surgical site infection risk index.**

Risk points	Risks
0 – 3 risk points 1 point	*1) American Society of Anesthesiologists (ASA) score 3 or more* *1= normal healthy patient* *2= patient having mild systemic disease* *3= patient having severe systemic disease* *4= patient having severe systemic disease with constant threat of life* *5= moribund patient not expected to survive without surgery*
1 point	*2) Contamined or dirty wound class*
1 point	*3) Operation lasting for longer than T hours (representing procedure specific 75th percentile of the duration of the operation)*

* Modified from [1]= *Culver et al. 1991;* [2]= *Horan et al. 1992;* [3]=*Horan & Emori 1997;* [4]=*de Blacam* et al. *2012.*

2.1.3 SURGICAL SITE INFECTION SURVEILLANCE METHODS

The traditional SSI surveillance methods (reported, for example, by Glenister et al. 1991) requiring ward rounds for reviewing nursing and medical records, temperature charts, drug prescriptions, and laboratory findings are time-consuming. They have been replaced by less time-consuming but as efficient computer-assisted systems with laboratory-based screening and case confirmation by surgeons (Chalfine et al. 2006).

Brandt and associates (2006) calculated ward-specific SSI rates, taking into account the beginning of surveillance participation of each department. They created operation-specific multivariate models to predict the outcome with respect to SSI. The participation in surveillance was voluntary and anonymous, preventing the delivery of false or invalid data. The changes in "healthcare practices" were not controlled for and they were discussed to have a potential influence on the reduced SSI rates. Geubbels' group (2006) reported that it should be at the discretion of the hospital whether or not to complete the profounder evaluation of IC practices and implementation of IP guidelines after national SSI surveillance. Despite not controlling for clinical practices, they recommended surveillance as a tool for continuous quality improvement.

Discussions about the appropriateness of the SSI rates as quality indicators in surgical care continues. The SSI rate is considered a reliable measure of hospital quality when the number of cases is high enough to ensure the reliability of the follow-up (Kao et al. 2011). The insensitive surveillance strategies better demonstrate the interhospital SSI rate differences and reflect the true quality of care rather than differences in surveillance methodology (Ming et al. 2012).

2.1.4 SURGICAL SITE INFECTION RATES

There are variations in SSI rates and in their reporting (Table 3). Variations exist between operations and within the individual wound classes representing the infection status of the surgical site. Within wound class one

Table 3 *Examples of variations in surgical site infection (SSI) rates.*

Characteristics	SSI rate (%)	SSI types	Reference (Country)
Among 44 operations (N=6,167)*	3.3	65.5 % superficial 25.7 % deep incisional 5.8 % organ/space	Moro et al. 2005 (Italy)
Surveyed operations (n=12,885)*	6.3		Reilly et al. 2006 (Scotland)
Not surveyed operations (n=8,825)	2.6		
Surgical operations (N=200,207)	1.9	52.8 % superficial 32.6 % deep incisional 14.6 % organ/space	Couris et al. 2007 (France)
Gastrointestinal (n=1618)	3.6		
Obstetric/gynaecology (n=312)	1.7		
Orthopaedic/accident&emergency (n=778)	1.2		
Urology (n=222)	3.7		
Cardiothoracic (n=134)	2.4		
Vascular (n=149)	1.4		
Neurosurgery (n=73)	1.4		
Ophthalmology (n=29)	0.3		
Ear, nose,throat /stomatology (n=111)	1.0		
Others (n=342)	1.4		
Operations (N=26,837)*	1.1-4.8		Rioux et al. 2006 (France)
Orthopaedic	1.1		
Genouritonary	2.4		
Cardiovascular	2.6		
Gynaecology	3.4		
Gastrointestinal	4.8		
Other	2.7		
Age			
≤ 65	2.7		
> 65	4.9		
Sex			
Female	3.0		
Male	3.6		
ASA physical status score			
≤ 2	2.6		
> 2	7.5		
Altmeier wound class			
≤ 2	2.4		
> 2	8.9		
Preoperative hospitalisation			
< 48 hours	2.7		
≥ 48 hours	6.2		
Relative duration of surgery			
≤ 75th percentile	2.8		
> 75th percentile	5.7		
Emergency status of the surgery			
No	2.9		
Yes	5.5		
Endoscopic surgery			
No	3.6		
Yes	2.0		
Duration of follow up			
< 15 days	2.0		
≥ 15 days	3.6		
Surgical procedures (N=177,706)	1.1	36% superficial 64% deep incisional	Ming et al. 2012 (US)
Among inpatients (n=1,493)		62% superficial	
Among outpatients (n=426)			

**including breast operations*

(clean wound) operations, for example, the risk for SSI was 3.6 times higher in breast operations than in hip operations (Reilly et al. 2006). In a Spanish 6-year SSI follow-up study of 2,989 patients (Palma et al. 2006), an increased risk of death was identified among patients with contaminated or dirty wounds (2.4-fold risk) compared with clean or clean-contaminated wounds. The risk was 7.1-fold higher among patients with an ASA score of 3 or 4 compared with patients with an ASA of 1 or 2, and 1.8-fold higher for patients with a long operation time. In Scottish patients, the mean length of the hospital stay was reported to be longer with SSI (10.1 days) compared with patients without SSI (7.7 days) (Reilly et al. 2006).

In a study of Saeed et al. (2015), the overall SSI rates among 349,298 US community hospital inpatients was calculated using contemporary modifications to national surveillance procedures. The rates varied widely within five of the 40 NHSN categories in 90-day follow-up time, the lowest being in breast surgery (3.6%) and highest in colon surgery (19.2%).

Despite the variations in methods, a decrease in SSI rates is reported after active surveillance (Brandt et al. 2006). In a French 3-year follow-up, the "crude SSI incidence rate" decreased from 4.0% to 2.7%, within varying procedure groups (Rioux et al. 2006). In a 6-year follow-up, the decrease was from 3.8% to 1.7% (Rioux et al. 2007). During a 9-year follow-up, a 5% annual and 45% total decrease in SSI rates was reported in almost all of the 10 categories of surgery, taking into account the diversity in surgical patients and surgical settings (Couris et al. 2007).

2.1.5 RISK FACTORS FOR SURGICAL SITE INFECTIONS

Patient- and operation-related characteristics may influence the risk of SSI development (Table 4). The infection risks of surgical patients have been controlled for since the 19th century (Brewer 1915; Haley 1991). According to Haley (1991), the intrinsic infection risk includes factors that the surgical patient had before arriving to hospital. It does not include the risk factors assembled later by the quality of care the patient receives from the hospital personnel. One important and well-reasoned intrinsic factor is the microbial carriage of the patient (Mangram et al. 1999; Safdar et al. 2003; Alexander et al. 2011). In addition to microbes, the patients' medication may also be associated with complications regarding wound healing (Gordon et al. 2009).

Several SSI risk factors related to patients' physical status have been identified. Reduced blood flow following haemorrhage may cause regional hypoxia, increasing the susceptibility of the patient for SSI (Chaudry & Ayala 1992). Low values of subcutaneous perfusion and oxygenation ($PsqO_2$) predicted SSIs better than the SENIC scores in a study of Hopf et al. (1997). Beltramini, Salata & Ray (2011) reported an increased rate of SSI and mortality among hypothermic patients. Diabetes mellitus, age and male sex were risks for SSI in a large German study (Kamph et al. 1997).

Table 4 *Potential patient and operation related risk factors for surgical site infections.**

Patient related risk factors for surgical site infections
Age
Male gender
Nutritional status
Diabetes
Smoking
Obesity
Coexistent infections at a remote body site
Colonization with microorganisms
Altered immune response
Length of preoperative stay in hospital
Medication
Hypothermia
Reduced blood flow following hemorrhage
Reduced subcutaneous perfusion and oxygenation
Operation related risk factors for surgical site infections
Preoperative skin preparations
Preoperative shaving
Skin antisepsis
Duration of surgical scrub
Duration of operation
Antimicrobial prophylaxis
Operating room ventilation
Inadequate sterilization of instruments
Foreign material in the surgical site
Surgical drains
Surgical technique
Poor hemostasis
Failure to obliterate dead space
Tissue trauma
Emergency of the operation
OT traffic

*Modified from Haley et al. 1985a; Haley 1991; Chaudry & Ayala 1992; Hyrylä 1993; Hopf et al. 1997; Kamph et al. 1997; Mangram et al. 1999; Safdar et al. 2003; Moro et al. 2005; Palma et al. 2006; Rioux et al. 2006 & 2007; Gordon et al. 2009; Couris et al. 2007; Alexander et al. 2011; Beltramini et al. 2011; Berríos-Torres et al. 2017.

In the SENIC project, an increased SSI risk was indicated for all operation types when the operation lasted more than two hours (Haley et al. 1985a; Haley 1991). The long duration of operation (in minutes), in addition to the emergency, gastrointestinal, and urological or multiple operations, have been reported as significant predictors for SSI (Couris et al. 2007). In a Finnish prospective study, an increased SSI risk was reported to be due to the presence of more than five persons working in the sterile field (2.8-fold) and if OT doors were opened more than eight times during the operation (Hyrylä 1993).

Several follow-up studies confirm the association between the type of operation, ward, size and type of hospital (medical teaching or non-teaching hospital) and SSIs (Kamph et al. 1997; Moro et al. 2005; Palma et al. 2006; Rioux et al. 2006 & 2007). In a study of Rioux, Grandbastien and Astagneau (2007), a preoperative hospitalisation duration of more than 48 hours also predicted an increased SSI risk.

2.1.6 SURGICAL SITE INFECTION RATES AND RISKS IN BREAST SURGERY

The SSI rates vary among procedures classified as "breast surgery" (Table 5). Breast surgeries are clean operations within which the expectation of SSI is low, but vary according to the patient risks and comorbidities, type of operation, perioperative therapy, and used surveillance time and methods (CDC 2004; Alexander et al. 2011; Xue et al. 2012; Davis et al. 2013). In US breast patients, SSIs are considered as preventable "never events" for which hospitals and physicians will not be reimbursed (Adetayo et al. 2012).

A meta-analysis of case-control studies on breast surgery completed by Xue et al. (2012) tested risk factors for SSI. Of 20 potential risks, 14 (increased age, hypertension, high body mass index (BMI), diabetes mellitus (DM), an ASA of 3 or 4, previous breast biopsy or operation, preoperative chemoradiation, conservation therapy versus other surgical approaches, haematoma, seroma, more intraoperative bleeding, postoperative drain, longer drainage time, and second drainage tube placed) were significant for SSI. Factors like smoking status, immediate reconstruction, axillary lymph node dissection, preoperative chemotherapy, corticosteroid usage and prophylactic antibiotic did not show statistical significance as a SSI risk. In a study of Davis et al. (2013), smoking was reported as a significant SSI risk among mastectomy patients. The SSI rates among patients with no documented NNIS risks varied between 0 and 1.86% (NNIS 1999; NNIS 2002; Reilly et al. 2006).

After a primary mastectomy, the SSI rates were lower than after reoperation (NNIS 1999; Moro et al. 2005; Rioux et al. 2007; de Blacam et al. 2012; Saeed et al. 2015; Olsen et al. 2015). The SSI rates in reconstructive breast surgery are higher than in traditional mastectomies (Saeed et al. 2015; Olsen et al. 2015). Reconstructions last longer and are more invasive than traditional breast operations, which may be part of the explanation. The work experience of the surgeon was reported as not influencing mastectomy complications, including SSI (Funnell et al. 1992). In a German 4-year follow-up study, the uppermost quartile duration of operation reportedly created a 3.6-fold higher risk; patients' wound class of 3 or more a 4.07-fold higher risk; and an ASA score of 3 or higher a 2.59-fold higher risk for postoperative SSI among mastectomy patients (Brandt et al. 2006).

The benefit of antimicrobial prophylaxis (AMP) among the breast-operated patients is vague (O'Connel & Rusby 2013; Jones et al. 2014). AMP administered as 24-hours in duration compared with post-mastectomy antimicrobial medication reduced SSI rates from 7.6% to 3.4% (Chen et al. 1991). AMP in the mastectomies of cancer patients (Bunn et al. 2006) and in breast reconstructions, both 24 hours and more (Liu et al. 2012), were managed without reductions in SSI rates. These results support the findings of Throckmorton et al. (2009) which reported no reduction in SSI rates among patients who received both pre- and postoperative AMP

compared with those with preoperative AMP only. Wagman et al. (1990) reported the AMP administration 30 minutes before the skin

Table 5 *Surgical site infection rates and risks in breast operations.*

Type and number (N) of operations	SSI rate (%)	Risks, operation and follow-up characteristics	Reference
Mastectomy (N=9,486)	1.7	Risk index 0,1	NNIS system October 1986 – April1998
(N=665)	5.0	Risk index 2,3 Duration cut point 2 h	NNIS 1999 (US)
Mastectomy (N=11,178)	2.1	Risk index 0,1	NNIS system January 1990 – May 1999
(N=403)	4.0	Risk index 2,3 Duration cut point 3 h	NNIS 1999 (US)
Mastectomy (N=13,623)	1.9	Risk index 0	NNIS system January 1992 – June 2002
(N=8,509)	2.3	Risk index 1	NNIS 2002 (US)
(N=835)	3.4	Risk index 2,3 Duration cut point 3 h	
Mastectomy (N=16,287)	1.8	Risk index 0	NNIS 2004 January 1992 – June 2004
(N=10,700)	2.2	Risk index 1	NNIS 2004 (US
(N=1,112)	3.4	Risk index 2-3 Duration cut point 3 h	
Mastectomy (N=311)	1.9	NNIS risk index 0-1	Moro et al. 2005 (Italy)
	3.0	NNIS risk index 2-3	
Mastectomy (N=7449)	1 -1.7	4-year surveillance	Brandt et al. 2006 (Germany)
Breast operations (N=1,338)			
PDS completed (n=1,122)	8.9		Reilly et al. 2006 (UK)
No PDS completed (n=216)	0.9		
(n=752)	7.4	NNIS risk 0, PDS	
(n=104)	0	NNIS risk 0, no PDS	
(n=174)	18.4	NNIS risk ≥1, PDS	
(n=27)	3.7	NNIS risk ≥1, no PDS	
Mastectomy / mammary tumorectomy (n=2,438)	2.7		Rioux et al. 2007 (France)
Breast operations (N=949)			
Mastectomy + implant	12.4	Risks: DM, BMI > 30, implant, central venous catheter	Olsen et al. 2008 (US)
Mastectomy + reconstruction	6.2		
Mastectomy only	4.4		
Breast reduction	1.1		
Breast cancer operations (N=2,338)	18.9	Risks: chemo radiation, hematoma, BMI >30 Duration cut point > 3h	Vilar-Compte et al. 2009 (Mexico)
Breast cancer operations (N=199)	19.1	Risks: high BMI, DM, smoking, skin disorder, tumour at high stage, neoadjuvant therapy	Angarita et al. 2011 (Columbia)
Breast reconstructions (N=297)	7.7	Risks: high BMI; DM	Adetayo et al. 2012 (US)
Breast operations (N=26,988)	5.6	High BMI, Smoking, DM, previous re-operation	de Blacam et al. 2012 (US)
Mastectomy (n=10,471)	4.0		
Lumpectomy (n=16,517)	1.6		
Mastectomy no reconstruction (N=38,739)	2.3	Risks: BMI >25; ASA ≥3; DM; operation time> 75th percentile (> 2 h), smoking	Davis et al. 2013 (US)
Breast-conserving operations			
Primary operation (n=23,001)	1.8	90 day SSI rate	Olsen et al. 2015 (US)
Re-operation (n=5,826)	2.4		
Breast operations (N=72,058)	3.6		
Mastectomy (n=3,447)	2.3	90 day SSI-rate	Saeed et al. 2015 (US)
Mastectomy + flap (n=4,065)	4.8		
Mastectomy + implant (n=18,300)	5.1		

BMI= body mass index; DM = Diabetes Mellitus; PDS = Post Discharge Surveillance

incision as not reducing SSI rates, but prolonging the SSI onset. More operation-specific research regarding AMP is needed (Ng et al. 2007; Acuna et al. 2012; Jones et al. 2014).

Factors potentially biasing the SSI rates in breast operation surveillance were smoking status of the patient, varying use of AMP and drainage, types of operations with differences in surgical technique, operation times and operation settings (Platt et al. 1990; Couris et al. 2007; Olsen et al. 2008; Vilar-Compte et al. 2009; Alexander et al. 2011; Andeweg et al. 2011; Angarita et al. 2011; Acuna et al. 2012; Xue et al. 2012; O'Connel & Rusby 2013; Saeed et al. 2015). According to Saeed et al. (2015) currently in the US, most of the conserving breast procedures are completed in outpatient settings. The younger and healthier private plastic surgery patients biased the SSI follow-up results, being less prone to SSI than patients in public settings. The unification of more than one multi-institute registers including significantly different patient populations may provide valuable complementary information for evidence-based decision-making in breast surgery (Khavanin et al. 2015).

2.2 PREOPERATIVE ASEPTIC PRACTICES

Preoperative aseptic practices are crucial for wound healing and success of intraoperative IP and IC. In SSI prevention, the focus has long been on the reduction of the patient-related SSI risks, the duration of the operation and the contamination of the surgical wound (Haley 1985a & 1991). Some of the preoperative AP measures, like preoperative full body showering and operation site hair removal by clippers, is considered standardised care (Beckman et al. 2011; Bryan & Yarbrough 2013; Munday et al. 2014). The most recent CDC guidelines for SSI prevention (Berríos-Torres et al. 2017) found the timing of preoperative showering unresolved. A Cochrane database systematic review by Tanner, Norrie and Melen (2011) found no statistically significant effect on SSI rates of hair removal. Confidence in a conclusion was not reached due to insufficient numbers of people involved in the research. Authors reported use of hair clippers associating with fewer SSIs than razors. There was no significant difference in SSI rates between depilatory creams and shaving, or between shaving and clipping the day before surgery or on the day of surgery. A Cochrane Review by Webster and Osborne (2015) provides no clear evidence of benefit for preoperative showering or bathing with chlorhexidine over other wash products to reduce SSIs.

The WHO's Surgical Safety Checklist (2009) includes two rough AP- related criteria. The first, for the preoperative phase, is: "Has antibiotic prophylaxis been given within the last 60 minutes?" and the second, for the intraoperative phase, is: "Has sterility (including indicator results) been confirmed?". After the implementation of the WHO Check List, a statistically significant decrease in SSI rates, from 20.5% to 3.6%, was reported in one hospital (Haynes et al. 2009). Adequate check

lists are also used in improving communication and promoting OT team cohesion (Lingard et al. 2002: Lingard et al. 2004; Lingard et al. 2005) and in reporting inadequate AP as systematic rather than human errors (Kim et al. 2007; Gillespie et al. 2012).

2.3 INTRAOPERATIVE ASEPTIC PRACTICES

Development of "asepsis" as a means to protect the "sterile field" has been documented since the mid-19th century. "Asepsis" has been a focus for protecting surgical patients since the times when it was safer to recover in an animal stable than in a public hospital (Cohen 1999). Lister generated "asepsis" to prevent surgical patients against the threat of wound fever caused by gangraena nosocomialis (Lister 1870a). He combined airborne and handborne contamination control into an "antiseptic system". Duguid and Wallace (1948) reported tests on OTs focusing on "dust-borne air-infection and droplet-nucleous air-infection protection by comparing intraoperative gown use and no-use". A large number of the particles (1000/minute) were counted during slight activity as well as during "marching" (10.000/ minute). Some of the particles were reported as remaining in the air for half an hour.

After the 1960s, "new working routines" in European operating suites were facilitated by designing the suites into four zones. The 1) protective zone, 2) clean zone, 3) sterile zone, and 4) disposal zone were introduced by The Operating Theatre Hygiene Subcommittee of the Medical research council in England to decrease the frequency of infections (Hambraeus & Laurell 1980).

The historical elements of "asepsis" (Lister 1870a&b; Brewer 1915; Duguid & Wallace 1948) are also present in quite recent medical (Campbell et al. 1993; Davis et al. 1999; Edmiston et al. 2005) and nursing studies (Crow & Taylor 1983; Kasal 1985; Eccleston 1992; Gautier et al. 1993; Radke & Ford 1993) evaluating the establishment and maintenance of the sterile field by "aseptic technique". The disestablishment of the sterile field was not a focus of clinical improvement at the old days.

Since the 1970s, in addition to airborne (Lidwell & Mackintosh 1978) and contact contamination (Davis et al. 1999) the research also focused on the body fluids, especially bloodborne infections (McCormick et al. 1991; Lowitt 1992; Saghafi et al. 1992; Heinsohn & Jewitt 1993; Nelsing et al. 1993; Short & Bell 1993; White & Lynch 1993; Telford & Quebbeman 1993; Schaffner & Mishu-Allos 1995; Lymer et al. 1997; Hoffman et al. 1999) due to the risks for human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) virus contaminations. Surgical aerosols, smoke (Hallmo & Naess 1991), vapours (Choy et al. 1987; Chosky et al. 1996), and particles of various origins carried by turbulent air currents (Barrett & Garber 2003; Friberg, Friberg & Burman 1999a & b; Friberg & Friberg 2005) into or near the sterile field were identified as infection risks for both patients and personnel.

Currently, the purpose of intraoperative AP is still to prevent and control the air-, blood- and body fluid borne, contact and vector contamination of the

surgical patients, personnel and environment before, during and immediately after invasive surgical procedures by the establishment, maintenance and disestablishment of the sterile operation field (Flaherty & Wick 1993; Telford & Quebbeman 1993; Mangram et al. 1999; EU Council 2009; EU Council 2010; Alexander et al. 2011; Berríos-Torres et al. 2017).

Prevention and control of SSIs by cutting the routes of contamination in the operated patients, OT environment and surgical personnel are all essential in improving surgical safety (AORN 1991 - 2013; Hallmo & Naess 1991; Wright & McGree 1993; Stafford et al. 1995; Allegranzi et al. 2011; Onwubiko et al. 2014). The EU Council (2009) published recommendations on patient safety including the prevention and control of HAIs at national, regional and local levels. The core requirements in the EU document from the AP viewpoint are: to make guidelines and recommendations available, to encourage adherence to prevention and control measures, and to surveil the incidences of the targeted infection types, accompanied by process and structure indicators, to evaluate the implementation of IC measures.

2.3.1 INTRAOPERATIVE ASEPTIC PRACTICES AND SURGICAL SITE INFECTIONS

The association between SSI and AP is difficult to investigate and prove (Pan et al. 2009; Saint et al. 2013; Berríos-Torres et al. 2017). Despite the challenges in comparing the evidence and methods presented at different levels, it is important to survey practices in the OT. The existing literature (e.g., Jarvis et al. 1991; Mangram et al. 1999; Reichman & Greenberg 2009; Archibald & Jarvis 2011; Berríos-Torres et al. 2017) is important to respect in controlling infections and maximising the beneficial surgical outcomes.

From time to time, SSI outbreaks due to contaminated products (Mastro et al. 1990; Jarvis et al. 1991) or surgical personnel (Schaffner & Mishu-Allos 1995; Allen et al. 1997; Kolmos et al. 1998; Bitkover et al. 2000; McNeil et al. 2001; Barbos et al. 2010) are reported. According to the CDC (Jarvis et al. 1991; Archibald & Jarvis 2011), both reusable and single-use disposable medical equipment can contribute to outbreaks through misuse (e.g., the reuse of devices intended for single use) and inadequate disinfection or sterilisation of reusable devices, or manufacturing defects.

Environmental factors including the healthcare facilities and surroundings, water reservoirs, potable water and waste disposal may contain clusters of *Legionella* species related to pulmonary infections or invasive *Aspergillus* species related to SSIs, especially among immunocompromised patients (Jarvis et al. 1991; Archibald & Jarvis 2011). These episodes rationalise the importance of the intraoperative APs. The consequences of lacking AP recommendation adherence may cause human suffering and increased healthcare costs. In the microbial carrier instances, eradication treatments are important to apply in household contacts too. The cleansing of household surfaces may take years (Kniehl et al. 2005).

According to Jarvis et al. (1998), in the nosocomial (later HAI) outbreak investigation of the CDC, the proportion of outbreaks related to products, procedures or devices increased 46.6% between 1980 and 1985. Between 1986 and 1990, the increase was 67% respectively. The proportion of device-related outbreaks only increased from 8.2% to 25.9% between 1986 and 1990, however. In 1998, the reported SSI outbreaks were due to contaminated red blood cells, povidone–iodine disinfectant, gentian violet skin marking solution, as well as water used to irrigate patients' ears and suction equipment, and processing instruments in ultrasound baths. In 2012, Dancer et al. reported deep SSI outbreaks after orthopaedic and ophthalmology surgery due to the inadequate maintenance of autoclave components, poor handling practices and lapses in the inspection of surgical sets by theatre staff.

Both uncommon and classical operations-related SSI risk factors, like long duration of operations (Emori et al. 1991; CDC 2004), require more detailed investigation from AP and patient safety perspectives (Gillespie et al. 2012). Due to lacking reliable reporting, it is difficult to assess the relationship between AP and SSI. This provides reasoning to include intraoperative AP as part of perioperative documentation. In some countries, the breaks in AP are recommended to be documented intraoperatively (Emori et al. 1991), in other countries, like Finland they are not recommended to be documented systematically (Anttila et al. 2010).

2.3.2 INTRAOPERATIVE EXPOSURE TO INFECTIONS

OT team members implement IP and IC measures against air-, blood-, contact-, droplet-, and vectorborne microbial contaminations protecting the surgical patient, environment and themselves. The most harmful exposures are those to bloodborne viruses: HIV, HBV and HCV. Among Western OT personnel, blood contact rates between 5 and 12% were reported in the 1990s and early 2000's (Short & Bell 1993; White & Lynch 1993; Beekman et al. 2001). Saghafi et al. (1992) reported rates of needlestick injury of approximately 2.8 per year. In 1998, in a Danish hospital, the HIV (0%), HCV (0.14) and HBV (1.6%) infection prevalences among healthcare workers was low, even the percutaneous exposure to blood was 1.5 per person-year (Fisker et al. 2004).

Canadian surgeons and residents reported an average of 3.3 surgical percutaneous injuries per year. The number of injuries per year was the highest in cardiothoracic (8.3) and vascular surgery (10.4) (Haines et al. 2011). In hip and knee arthroplasty operations, the glove perforation risk for the surgeon was significantly higher during the first half of the operation than during the second half. Of the perforations, 57.8% were at the index finger and thumb. Of the perforations, 18.4% were outer and 8.4% inner glove perforations. The second digit of the non-dominant hand was the most frequent site of perforation (25.5%) (Demircay et al. 2010). Among US otorhinolaryngologists, the exposure episodes to blood , althouhg under

reported, were reported by 26.6% of them had experienced sharps injuries (Vijendren et al. 2016). The majority of underreported exposure to blood were injuries by needlestick or cannula in hands, cutting, blood on non-intact or intact skin and eyes (Jagger et al. 1998; Lymer et al. 1997).

In 2010, almost half of the Cypriot nurses had at least one incidence of occupational exposure to pathogens. More than 20% of the exposed nurses had more than one mode of exposure (Efstathiou et al. 2013). In Japan, the sharp injuries (6.2 per 100 occupied beds) occurred most often in patient rooms and OTs. The injury rates were highest at large hospitals; in workers aged less than 40 years injuries occurred during the use of medical devices, mainly disposable syringes and suture needles (Yoshikawa et al. 2013).

In Iranian hospitals, 89.3% of the personnel reported needlestick and sharps injuries at some stage in their career. Of them, 70.2% had experienced between one and five injuries, 16.7% between five and ten and 2.3% more than ten injuries. Most of the injuries occurred during suturing (31.7%), injection or aspirating (17.2%), and passing or receiving instruments (15.7%) (Lakbala et al. 2014). In one Northeast Ethiopian hospital, 32.8% of the healthcare personnel were exposed to sharps injury. Among those who had no on-the-job training, the sharps injury was 4.7 times more likely in comparison with those who had on-the-job training. The healthcare workers who had previous exposure to sharps injuries were 3.7 times more likely to sustain an injury compared with those who were not previously exposed (Sharew et al. 2017). In an Indian hospital (Aggarwal et al. 2012), 74.3% of the exposed had not followed the clinical safety measures. Of the exposed, 24.3% did not use gloves, 14.6% recapped needles, 7.3% did not wear gloves in recapping needles and 28.0% sustained the injuries during sweeping or discarding sharps not disposed at the source site as recommended.

In the US, the Needlestick Safety and Prevention Act of 2000 mandated the requirement to provide safety-engineered devices. The injury rates measured in 1993 and 2006, dropped 31.6% in nonsurgical settings, but increased 6.5% in surgical settings. Of 31,324 total sharps injuries, 7,186 were among surgical personnel. Suture needles (43.4%), scalpel blades (17%), and syringes (12%) caused most of them. Seventy-five percent of injuries occurred during the use or passing of devices. Devices originally used by others, most often surgeons and residents, typically caused injuries of nurses and surgical technicians (Jagger et al. 2010). In the UK, the Health Protection Agency (2012) reported occupational exposure rates of 9% among porters, security and housekeeping staff, showing minimal change over time between 2002 and 2011. Most of the exposures among ancillary staff not directly involving inpatient care were percutaneous exposures caused by inappropriately discarded needles.

The relatively high occupational risk for bloodborne viruses stresses the effective use of the surgical barriers and qualities of barrier materials (Moylan et al. 1987; Werner et al. 1991; Flaherty & Wick 1993; Modak et al. 1992; Duncan & Batchelor 1993; Larson et al. 1991; Zinner 1994; Belkin 1997; Culver

1997; Leonas & Jinkins 1997; Mendelson et al. 1997; Jagger et al. 1998; Urech 2000; Bible et al. 2009).

2.3.3. GUIDELINES AND RECOMMENDATIONS FOR INTRAOPERATIVE ASEPTIC PRACTICES

Guidelines for clinical practice are systematically developed statements created in order to assist in practitioner decisions regarding the appropriate healthcare for specific clinical circumstances and patients (Cabana et al. 1999). Guidelines have a stronger evidence-base than recommendations.

The AORN Recommended Practices are the most widely known intraoperative AP recommendations. The contents and foci of the AORN 2013 AP recommendations basing on systematic review, vary from the earlier versions (AORN 1991; AORN 1993; AORN 1999; AORN 2001; AORN 2006) representing what is believed to be an optimal level of practice. In the AORN 2013 edition, nine recommended practices focus on the sterile technique. They recommend implementation of the specific actions and activities to prevent contamination and to maintain sterility of identified areas during operative and other invasive procedures and safe environment of care. In the 1999 AORN edition, intraoperative AP recommendations were introduced as part of recommendations for use of surgical attire, environmental cleaning in the surgical practice setting, use and selection of gowns, drapes and barrier materials, surgical hand scrubbing, hazards in the surgical environment, patient skin preparation, evaluation and selection of surgical products and medical devices, maintaining sterile field and sterilisation in the practice setting.

CDC guidelines, introduced in 1999 (Mangram et al. 1999) and updated in 2016 (CDC 2016 a&b, Berríos-Torres et al. 2017), are the most common guidelines used in surgical IP and IC (Table 6). They were created for the prevention of SSIs, providing techniques for handling air; cleaning environmental surfaces; sterilising surgical items; and supporting the clinical activities of the surgical team members, like handling drapes and performing surgical asepsis (Jalovaara & Puranen 1989; Mangram et al. 1999; Alexander et al. 2011). Only a few specific intraoperative AP recommendations (to limiting OT traffic and conversation during operation as activities of surgical team members) existed in the CDC (2016a) guidelines. Numerous unresolved recommendations existed in the most recent version, after using grading in the quality assessment of the research articles providing the foundation for the guidelines (Berríos-Torres et al. 2017). The guidelines include an online tool: "The CDC Infection Prevention and Control Assessment Tool for Acute Care Hospitals" (2016b).

The quality and quantity of the evidence supporting the updated CDC guidelines (2016a) for surgical IC and IP varied much. Limited evidence existed for the several technical and behavioural practices, for example, regarding some commercially-distributed equipment or administration of

AMP. Use of commercial products, like incise drapes, are reported with debatable evidence (Fleischman et al. 1996; Pabon et al. 2010; Falk-Brynhildsen et al. 2012).

The CDC guidelines (2016a) represent a limited portion of the overall performance of the intraoperative AP due to lacking evidence. The overall criteria of the CDC (2016b) online tool for assessing SSI prevention and control are: 1) preoperative timing of AMP administration; 2) appropriate prophylactic antibiotic selection based on procedure type; 3) discontinuation of prophylactic antibiotics; and 4) prompt removal of urinary catheter. Acute hospitals are guided to routinely audit (monitor and document) adherence to recommended IC practices for SSI prevention: a) adherence to preoperative surgical scrub and hand hygiene, b) appropriate use of surgical attire and drapes, c) adherence to aseptic technique and sterile field, d) proper ventilation requirements in surgical suite; e) minimisation of traffic in the operating room, and f) adherence to cleaning and disinfection of environmental surfaces.

Like the CDC guidelines (2016a), the updated WHO recommendations (Storr et al. 2017) are also mainly focused on the core components of effective IP and IC programmes. The evidence-based guidelines for hand hygiene was introduced as the only clinical procedure. In the programme implementation, the WHO working group pointed out the adaptation of the guidelines into the local context, advising taking into account the available resources, culture and public health needs as well as the feasibility and costs in low resource settings. The work group required that sound implementation strategies and practical tools should facilitate the programme adoption, but it does not introduce them for clinical use.

In the UK, intraoperative IP and IC measures are recommended to be adopted for specific procedures in individual patients after "suitable and sufficient" risk assessment. According to the Hospital Infection Society (HIS) Working Party on Infection Control in Operating Theatres, the measures could be based on the likelihood of the presence of an infectious agent, the nature of the infectious agent (i.e., how infectious it is) and the likelihood of dispersion (splashing, dispersal by power tools). The UK recommendations are based on insufficient evidence. Some recommendations are reasoned with only one reference. No evidence was introduced about perforated surgical gloves increasing the incidence of SSI. Unlike other authors (e.g., Tanner & Parkinson 2006), they recommended that a perforated glove is not an indication to change gloves. They also recommend that wedding rings are not necessary to remove and no hair cover is needed in the OT outside the sterile field during operations other than orthopaedic prosthesis operations. (Woodhead et al. 2002.)

Some of the intraoperative APs, like surgical site disinfection, have competing procedures that are also involved in an ongoing search for evidence and cost-effectiveness (Parienti et al. 2002; Al-Naami et al. 2009; Magalini et al. 2013; Berríos-Torres et al. 2017). A well-documented but expensive

practice, laminar airflow over the sterile surgical field, has been challenged by analysis comparing its cost-effectiveness with AMP and antibiotic impregnated cement in hip arthroplasty (Merrollini et al. 2013). When modern ventilated gowning setups were compared with conventional surgical gowns and gloves in the prevention of staff-sourced contamination in orthopaedic operations, no benefit was found by using the expensive setups (Fraser et al. 2015).

The existing guidelines for the intraoperative AP in the sterile operation field focus on procedural practices (Blomgren et al. 1990; Stafford et al. 1995; Mangram et al. 1999; Rowley & Clare 2009; Alexander et al. 2011; SIGN 2014), safety instructions (Gerberding 1993; American College of Surgeons 2007, Royal College of Nursing 2013) and overall perioperative AP (AORN 2013).

Table 6 *Recommendations for reducing surgical site infections.*

Recommendation for*	Nature of the recommendation
Patient stop smoking before operation	Preparation of the patient
Preoperative shower in the evening before and morning of an operation day	Preparation of the patient
Preoperative hair removal using clipper immediately before operation or not removing the hair	Preparation of the patient
Decontamination of the incision area with povacrylex / alcohol or chlorhexidine / alcohol-based product	Preparation of the patient
Use of prophylactic topical antimicrobials (in-wound and nasal)	Preparation of the patient
Use of high efficiency particulate air (HEPA) filters	OT Environmental
Laminar airflow system	OT Environmental
Limiting OT traffic	Aseptic behavior
Limiting conversation to idle	Aseptic behavior
Skin decontamination	Preparation of the patient
Administration of procedure specific, adequately timed (30 min. before incision) single dose or 24 hours systemic AMP	Preparation of the patient
2-3 min. hand decontamination with antiseptic agents	Preparation of the personnel
Preventing glove perforations	Aseptic technique
Protecting strike-through in operating gowns	Aseptic technique
Avoiding tissue damage and foreign bodies (electrocautery, dead spaces in wound closure)	Surgical technique
Use of closed drains	Selection of the materials Surgical technique
Improvement of host defence influence of body temperature	Patient care-related IP measure
Oxygen therapy of the surgical patient	Patient care-related IP measure
Glucose control of the surgical patient	Patient care-related IP measure
Limited / adequate transfusions and fluid administration	Patient care-related IP measure
Delayed primary closure of contaminated wound	Patient care-related IP measure

* CDC 2016b; Berríos-Torres et al. 2017.
AMP = antimicrobial prophylaxis, IP = infection prevention, OT = operating theatre

They represent a fragmented, and in some cases limited, part of the measures for intraoperative AP. There are challenges in testing evidence supporting the implementations of the intraoperative AP recommendations, but the implementation may be cost-effective when compared with treating SSIs. Before arriving at conclusions, it is important to reach a consensus about standardised designs and models for comparative research.

Preparation of the patient for the operation

Preparation of patients for the operation starts before the operation by improving the immunological response of the patients by proper nutrition, blood glucose and protein levels, stopping smoking, and most of all maximising the hygiene of the surgical site (Mangram 1999; Woodhead et al. 2002; Alexander et al. 2011). When needed for eradication, topical and systemic antimicrobials are prescribed. Meticillin-resistant *Staphylococcus aureus* cross-infection is reported to be transmitted via the face of hospital patients, necessitating the eradication of the microbial growth before operation (Kuramoto-Chikamatsu et al. 2007). The AMP is recommended to manage 30 minutes before the skin incision (Alexander et al. 2011; SIGN 2014; Berríos-Torres et al. 2017).

Microbial growth on the surgical patient's skin may contaminate the hands of the caregivers, OT air, equipment used and surgical textiles. After preoperative preparations, careful skin disinfection is performed to reduce contamination of the surgical site (AORN 1991-2013; McCullough 1993; Mangram et al. 1999; Tammelin et al. 2001; Tammelin et al. 2012; Tanner et al. 2006; Berríos-Torres et al. 2017). Development of more effective measures in reducing skin flora is continuously ongoing (Pabon et al. 2010). Completing the preparation of the patient's skin for operation, the use of sterile or clean skin preparation kits are recommended (AORN 1991-2013; Gautier et al. 1993). Choosing air-free patient warming devices is recommended over forced air warming devices, particularly for orthopaedic procedures, because the forced air warming devices disrupt the ultra clean airflow system and challenge the sterility of the surgical site (McGovern et al. 2011).

Aseptic practices securing the surgical environment

For security reasons, the operating department was divided into four zones, excluding corridors and a transfer area (Humphreys 1993). The zonal layout focuses attention on the importance of good practices as one approaches the operating field. The layout aims at inhibiting the entry of non-essential personnel to the clean areas of the OT suite and promotes OT discipline. The *aseptic zone* includes an OT itself and a layout room. The *clean zone* includes the anaesthetic room and scrub-up area. The *protective zone* includes the entrance area, recovery room and changing facilities. The sink or sluice rooms are located in the *disposal zone*. In the OT, the doors are recommended to be kept closed or self-sealed, windows to be hermetically sealed and accessible for cleaning, the floors of durable material and horizontal ledges avoided. Appendix 1 includes a summary of recommended AP according to the four-zone model.

OT air is recommended to be filtered so that in conventionally ventilated areas particles >5 μm are removed by 20 air changes per hour to obtain 50-

150 colony-forming units (CFU)/m^3 bacterial counts. In orthopaedic OTs, particles smaller than 3 μm are recommended to be removed by high-efficiency particulate air (HEPA) filters (Dharan & Pittet 2002). According to Friberg and Friberg (2005), working in the sterile field under an ultra-clean laminar airflow is recommended to be performed following the three zone OT model. The ultra-clean laminar airflow of 0.4 m/s is placed to secure that the "wound area" is surrounded by the clean area with an airflow of 0.2 m/s. The remaining semi-clean area is regarded as contaminated. (Friberg, Friberg & Burman 1999a&b; Friberg & Friberg 2005.) The different zones are recommended to be marked on the floor (de Korne et al. 2012) to facilitate the maintenance of uninterrupted air currents.

Various models for securing OT air were tested (Cole & Cook 1998; Friberg et al. 1998; Friberg et al. 1996; Friberg et al. 1999a&b; Friberg, Friberg, Burman, Lundholm & Östeson 1996; Friberg et al. 2001) for the benefit of laminar airflow in reducing CFU and particle dispersion within the airflow. The association between laminar airflow and reduction in SSI rates is questioned at this time (Smyth et al. 2005; Brandt et al. 2008; Merrollini et al. 2013; Bischoff et al. 2017). Despite variations in study set-ups and biases in study groups (no body exhaust systems were used in the study of Brandt et al. 2008), biases in the selection of operations in the study of Bischoff et al. (2017), the lack of controlling for AP-related practices and use of powered devices in controlling the maintenance of the uninterrupted air currents during the operation, the authors challenged the benefit of laminar airflow due to their high building expenses. In Finland building laminar flow in new buildings is considered more cost-effective than building during renovations (Rantala 2009).

Stocks et al. (2011) has reported the portable directed airflow system in reducing bacterial counts at the surgical site to the recommended level (10 CFU/m^3) and reducing the particle dispersion, but no evidence about its effect on SSIs was found. Bischoff et al. (2017) recommended not installing laminar airflow in new operating rooms as a preventive measure in reducing the risk of SSIs. The importance of well-functioning and correctly-designed heating, ventilation, and air-conditioning systems was demonstrated by an outbreak at an ambulatory surgical centre due to the intermittent functioning of the heating, ventilation, and air-conditioning systems (Archibald & Jarvis 2011). According to Clark and de Calcina-Goff (2009), improvements in contamination control and designing new hospitals are required.

The updated evidence-based Canadian guidelines (Alblas et al. 2017) for OT cleaning verified and specified the Finnish recommendations (Anttila et al. 2010) and updated for example the HIS 2002 guidelines (Woodhead et al. 2002). They include the cleaning schedule addressing preliminary cleaning, end-of-procedure cleaning, terminal cleaning, weekly cleaning, monthly cleaning and recommendations for specialty equipment. They divide operating department to unrestricted, semi-restricted and restricted areas. Surgical or invasive procedures are performed in restrict areas. The surgical

team shares the responsibility and accountability for ensuring a clean environment for each patient. During cleaning the personnel wears appropriate Personal Protective Equipment (PPE), like masks, gloves and gowns. Chosen disinfectant products should be targeted according to microorganisms. The cleaning should start at higher surfaces and works down in a clockwise manner by using reusable or single use low-lint cleaning materials. Floor cleaning progresses from cleanest area to dirtiest, from perimeter of the room to the centre. Theatre lights should be inspected for cleanliness. Equipment stored in the OT should be kept to a minimum and doors closed during cleaning. OT nurses should visually inspect the OT for cleanliness before the case carts, supplies, and equipment are brought into the room. The equipment should damp dust before brought into or out of the OT theatre. Those leaving the OT should be cleaned and disinfected with disinfectant. The Finnish recommendations stress the importance of hand hygien during cleaning (Anttila et al. 2010).

During intraoperative phase the responsibility for verifying disinfection of a contaminated surface rests with the surgical team member who is first aware of the contamination. All contaminated (by blood, body fluids, or other potentially infectious material) items or surfaces occurring intraoperatively are to be immediately cleaned and disinfected. The containers for spillage cleaning materials should be emptied after each use. Chemical spills occurring intra-operatively should be managed according to regional and national policies and procedures. (Woodhead et al. 2002; Anttila et al. 2010; Alblas et al. 2017).

OT waste includes biological material, and the disposal and decontamination of it is crucial in maintaining environmental security (Blenkharn 1995; Kanemitsu et al. 2005). Appropriate segregation of OT waste is cost-effective (Mosquera et al. 2014). Proper healthcare waste segregation is crucial in avoiding the waste-related exposures to bloodborne infections reported among both surgical and housekeeping personnel (Health Protection Agency 2012).

Preparation of the personnel working in the sterile field

Surgical team members protect the microbial contamination of the surgical patient and themselves by taking care of good personal hygiene, especially hand hygiene by avoiding working in the OT with non-intact skin and infectious diseases. They do not use personal jewellery or wristwatches. They change their working-unit-specific attire daily, use cleanable shoes, disposable masks and disposable non-linting hair covers (AORN 1991 - 2013). The bacterial colonisation of scrub suits used outside the OT reported large on waist and hip areas (Hee et al. 2014), potentially compromising the sterility of the surgical gown after liquid penetration during operation. Changing one's scrub suit used outside OT may be necessary in select operations and with vulnerable patients. Surgical team members use disposable masks, powered mouth and nose covers, according to the

procedural needs and the filtering capacity of the chosen equipment in the sterile field and presence of the sterile field (Ayliffe 1991; Mitchell & Hunt 1991; Berger et al. 1993; Prust 1995; McLure et al. 1998; Woodhead et al. 2002). By using respiratory protection equipment instead of a surgical mask, the scrubbed personnel prevent exposure to surgical smoke and aerosolised blood (Gatti et al. 1992; Heinsohn & Jewett 1993; Wright & McGree 1993; Barrett & Garber 2003).

The members of a scrubbed operating team are recommended to complete a surgical hand scrubbing, including a minimum two-minute hand wash and disinfection before donning the sterile gowns and surgical gloves (Kobayashi 1991; Pereira et al. 1990; Babb et al. 1991; Leyden et al. 1991; Nagai et al. 1993; Paulson 1994; Woodhead et al. 2002; Tanner, Swarbrook & Stuart 2006 &2016). The time of surgical hand disinfection depends on the disinfectants used (Kampf et al. 1998; Kampf et al. 2005). Even one's fingernail area is recommended to be scrubbed with a sterile atraumatic brush (Loeb et al. 1997), though no evidence supports its use in SSI reduction (Tanner, Swarbrook & Stuart 2006 & 2016). Sterile gloves are recommended to be donned at a table other than the instrument table to avoid the risk for contamination (Eccleston 1992; AORN 2013).

Immediately before the operation starts, the members of the sterile team should wear protective sterile gowns and gloves according to the procedural needs (Hill et al. 1974; Moylan et al. 1987; Blomgren et al. 1990; Smith & Nichols 1991; Prust 1995; Zinner 1994; Leonas & Jinkins 1997) and eye shields or goggles (Saghafi et al. 1992). Double or indicator gloves should be used at least in risky operations, where visible or microperforations in surgical gloves expose the patient or surgical personnel to microbial contamination (Sebold & Jordan 1993; Laine & Aarnio 2004; Tanner & Parkinson 2006; Tao & Basnet 2014). In high-risk operations, gloving with antimicrobial coverings is also recommended (Modak et al. 1992; Kampf et al. 1998; Guo et al. 2012; AORN 2013).

Aseptic practices in establishing the sterile field

The sterile operation area is recommended to be established as close to the start of the operation as possible (AORN 1991-2013; Campbell et al. 1993). Sterile equipment and textiles should be used to establish and maintain the sterile field on the surgical site (Klapes et al. 1987; AORN 1991-2013). It is preferred that sterile materials are stored in closed cabinets, rather than on open shelves in wrappers or containers, and handled as little as possible with extreme care and caution (Standard et al. 1971; Dancer et al. 2012).

Preparations for the operation start with the selection of materials and equipment used during the operation. The use of sterile equipment and materials is essential in preventing equipment-related infections (Gorse & Messner 1991; Woodhead et al. 2002). Materials and equipment used in the sterile field need to be tested according to accepted methodologies to maintain

the barrier effect in protecting the surgical patient and personnel (Jalovaara & Puranen 1989; McCullough 1993: Rutala & Weber 2001; Gulihar et al. 2009; Laki terveydenhuollon laitteista ja tarvikkeista 2010; Overcash 2012; AORN 2013). It is important to consider the cost-effectiveness and environmental sustainability of the material selection without compromising the surgical safety (Rutala & Weber 2001; Baykasoglu et al. 2009; Overcash 2012; AORN 2013).

The surgical gowns and additional surgical textile are recommended to be produced of lint-free and impermeable materials (Moylan et al. 1987; Verkkala et al. 1990; McCullough 1993; Hubble et al. 1996; Granzow et al. 1998; Woodhead et al. 2002; Gulihar et al. 2009; Tammelin et al. 2012; AORN 2013). According to Telford and Quebbeman (1993), the factors related to the selection of the sterile equipment and materials are: 1) the length of the operation; 2) the estimated blood loss; 3) the type of operation; 4) the blood exposure record of the personnel involved; 5) the comfort level desired; and 6) the cost of the garments. Operations lasting over two hours and more than 100 mls of blood loss result in a risk of blood exposure for the surgeon and the first assistant, requiring double gowning and reinforced surgical gowns.

The avoidance of powdered sterile gloves is important to prevent the formation of adhesions in abdominal surgery patients (Holmdal & Risberg 1997) and allergy in healthcare workers (Phillips et al. 2001). In preparing the sterile field after the final patient preparation, the contaminated gloves should be changed. The use of "scrubbed leg-holder" and double gloves during the preparation of the sterile field and changing the overgloves before application of the adhesive plastic drapes will reduce the number of CFUs in the orthopaedic operation field (Davis et al. 1999).

Aseptic technique in maintaining the sterile field

The present standards for working in the sterile operation field protected by exponential ultra-clean laminar airflow emphasise the importance of avoiding turbulent air currents causing surface contamination (Cole & Cook 1998; Friberg et al. 1998; Friberg et al. 2001; Friberg & Friberg 2005). In implementing the three-zone OT air model, Friberg and Friberg (2005) recommended avoiding bacterial dispersion into the sterile operational field and the wound area. They requested: 1) the OT personnel to stand downstream of the airflow in relation to the instruments when organising the sterile equipment and instruments; 2) performing all the sterile set-ups in the ultra-clean zone; and 3) moving the instrument tables into the semi-clean zone in a manner that maintains sterility (i.e., well covered) during and after positioning the patient. The adherence to these practices are not widely studied in clinical practice.

The dispersion of particles has been reported as elevated during the use of powered instruments (Blomgren et al. 1990; Davis et al. 1999; Woodhead et al. 2002; Liljeblad 2006c), patient tissues and skin, and sponges and surgical

textiles (Liljeblad 2006c). Using powered instruments, like suction, during operation may cause air contamination in the sterile field and is important to avoid or keep to a minimum. The use of sterile light handles disturbs the airflow (Davis et al. 1999). The airflow patterns are dependent on the relative positions of personnel, lamps and equipment and the contaminant dispersion is dependent on the locations of the contaminant sources. Temporal or extended periods of door opening, the movement of staff and equipment, and sudden bursts of particles from sneezes or coughs can be highly significant in compromising the ultra-clean OT air (Chow & Yang 2005; Liljeblad 2006c). It is important to keep the number of persons in the sterile field and door openings to a minimum. More than five scrubbed persons and doors opened more than eight times during operation increased the SSI risk (Hyrylä 1993).

In operations where heavy aerosol and surgical smoke production exists, additional evacuators and proper respirators are recommended (Heinsohn Jewett 1993; Barrett & Garber 2003). Evacuation of surgical smoke has been reported as an important protective measure in maintaining the sterility of the operational field and in preventing occupational exposure to infectious airborne particles (Gorse & Messner 1991; Gatti et al. 1992; Romig & Smalley 1997; Hensman et al. 1998).

Airflow studies recommend that surgical masks be used by unscrubbed members of personnel within three metres proximity of the sterile field in OTs with forced ventilation (Romney 2001). The position of the surgical mask covering both the nose and mouth is reported to be important in preventing microbial dispersion into the surgical wound area (Berger et al. 1993). According to Edmiston et al. (2005), the barrier properties of the surgical mask break down rapidly. They recommend changing it at intervals of 60 to 90 minutes. Proper squire hood-style disposable head covers and masks are reported to be minimise the emission of heavy particles (Friberg et al. 2001). The evidence related to surgical mask use requires further research (Lipp & Edwards 2002; Health Protection Scotland 2016; Vincent & Edwards 2016).

The operating gown can be contaminated during operation (Davis et al. 1999; Tammelin et al. 2012). Handling the sterile gown in the region between the chest and operative field, and any contact with the gown outside this area, including the elbow areas, is recommended to be avoided (Bible et al. 2009). Contact between the low-waist area and the operating field are recommended to be avoided due to the high bacterial counts in the low-waist area (Copp et al. 1986; Hee et al. 2014). Surgical gown penetration is a risk for intraoperative blood contact. Cao and Cloud (2010) reported warm liquids penetrating some surgical gown fabrics in higher quantity than is reported after standard laboratory tests using distilled water or synthetic blood reservoir at cooler. Repeated laundering reduces the barrier resistance of surgical gowns. Depending on the fabrics used, the gowns maintain their protection level up to 5-20 washing cycles in (Midha et al. 2014). The antibacterial finishing of the fabric is reported to sufficiently inhibit the growth of *S. aureus* bacteria for all fabric samples, maintaining its activity up to 20 washing cycles for all fabrics.

Recent nanotechnological innovations have improved the viral protection of surgical gowns (Parthasarathi & Thilagavathi 2015).

Surgical gloves are recommended not to be worn without changing for longer than two hours (Leitgeb et al. 2015) due to the increasing number of perforations (Kojima & Ohashi 2005; Bekele et al. 2017). Broken or soiled sterile gloves are recommended to be changed to avoid the contamination of the sterile field, equipment and items (Laine & Aarnio 2004; Tanner & Parkinson 2006; AORN 2013; Tao & Basnet 2014; Lee et al. 2015). The use of sterile light handles also causes frequent contact contaminations. Gloves are recommended to be changed after light handle manipulation (Davis et al. 1999). The amount of gloves used per operation are many, but their quality does not always meet clinical requirements. Leitgeb et al. (2015) reported a 41.1% total perforation rate of surgical gloves after emergency operations and 30.0% rate after elective surgeries. They covered the glove interior with chlorhexidine-gluconate coat and demonstrated more than 6 log10 in killing transient microorganisms such as *S. aureus* or *K. pneumoniae* within 5 min contact time following a 2-h wear time.

Double gloving is one of the evidence-based measures in preventing the patient against SSIs and the surgical personnel against bloodborne exposures during surgery (Tanner & Parkinson 2006; Mischke et al. 2014). Double gloves are particularly needed in orthopaedic operations (Demircay et al. 2010). A higher frequency of double gloving (75%) was reported in orthopaedic surgery when compared with other specialties (Haines et al. 2011).

The careful use and awareness of the requirements for surgical textile performances are important in protecting the barrier effect of the textiles. Penetraton of surgical drapes may expose the surgical site to microbial contamination originating from the skin of the patient or personnel, despite skin disinfection before draping (McCullough 1993; Blom et al. 2000; Blom et al. 2002a&b; Falk-Brynhildsen et al. 2012; Overcash 2012). It is possible to avoid bacterial penetration and perforation of the surgical barriers to a certain extent by controlling the blood loss, pressure, leaning, use of sharp items, and the length of the operation (Flaherty & Wick 1993; Blom et al. 2000; Rutala & Weber 2001; Tammelin et al. 2012; Overcash 2012; AORN 2013).

During clean-contaminated (e.g., gastrointestinal) operations, the handling of drapes in the area near the wound is to be avoided due to the bacterial contamination of the sterile barriers by wound area microbes (Whyte et al. 1992; Woodhead et al. 2002). The handling of equipment and sterile items in the sterile field should be limited. The hands of scrubbed personnel has been reported as important sources of microbes contaminating the surgical site and equipment used in the sterile field (Tammelin et al. 2001). The surgical blade is recommended to be changed after the patient skin incision. Of the suction tips, 11.4%, and 10% of the needles used in fascia closure were found contaminated in orthopaedic surgery and were recommended to be changed or discharged before continuing the operation (Davis et al. 1999). In avoiding exposure to bloodborne infections via

needlestick and sharp injuries by protecting the hands-free zone, using blunt sutures during the operation is recommended (Haiduven et al. 1999; American College of Surgeons 2007; Soldá et al. 2009; Royal College of Nursing 2013).

Bruen (2001) recommended implementing the clean and dirty technique: 1) using single set-ups, commence the surgery working from the intestinal tray; using isolated sponge holders, abdominal swabs and extra drapes around the wound side prior to the dissection; using a kidney dish or the Mayo table to isolate instruments as they are used on the bowl; and isolating used instruments, sutures and blades on the intestinal tray once the anastomosis is completed and until the operation is finished; 2) changing suction and diathermy prior to closure; 3) removing the cover from the Mayo table; and 4) cleaning swabs and drapes on the wound site prior to closure in gastrointestinal surgery, preventing the microbial contamination and spread of cancer cells. This technique was implemented as part of a unit-based surgical safety programme (Wick et al. 2012).

Aseptic technique in disestablishing the sterile field

During the discharge of the sterile field, both the scrubbed and unscrubbed personnel use gloves to protect hands from microbial contamination (Saghafi et al. 1992). The hands-free technique is recommended in handling sharp items to protect hands from injuries (McCormick et al. 1991; Telford & Quebbeman 1993; Jagger et al. 2010) and contamination (Davis et al. 1999). The use of nose and mouth covers may be useful in protecting personnel due to contaminated OT air (Edmiston et al. 2005).

Aseptic behaviour in the operating theatre

The three zone OT model (Friberg & Friberg 2005) is recommended to implement in avoiding the disturbances in the air currents and bacterial dispersion into the sterile operational field. Only the scrubbed persons are working in the ultra-clean zone (Appendix 1). The other members of personnel like the anaesthesia personnel and the circulating nurse stay outside the ultra-clean zone, in the semi-clean zone. The clean zone is recommended to be designated for opening and receiving sterile equipment, gowning and gloving. Equipment such as diathermy, suction, or a heart–lung perfusion machine is recommended to be placed in the clean zone. The unsterile surgical attire is recommended to be used outside the laminar airflow in the semi-clean zone. The opening of OT doors is recommended to be avoided so as not to disturb the laminar airflow (Hyrylä 1993; Bédard et al. 2015) and to control the bacterial dispersion from the skin of the patients and personnel into the OT air (Tammelin et al. 2001).

There is unsatisfactory evidence recommending the use of a cover gown for protecting scrub suits against bacterial contamination when OT personnel

visit outside the OT. The bacterial counts did not increase on scrub suits after anaesthesiologists visited outside the OT (Hee et al. 2014), but a decrease in bacterial colonisation of the right shoulder area of scrub suits was reported after using the cover gown. Changing scrub suits after visiting outside the OT requires clinical decision making on the basis of a cost-effective analysis (Copp et al. 1986; Mailhot et al 1987; Woodhead et al. 2002).

The use of plastic overshoes is recommended to avoid. The use may lead to a significant increase in floor colony counts, rather than a reduction and may contaminate hands when overshoes are put on or removed (Humphreys et al. 1991; Woodhead et al. 2002).

2.4 ADHERENCE TO INTRAOPERATIVE ASEPTIC PRACTICES

According to general assumption, all healthcare professionals, including surgical team members, aim for successful outcomes in patient care (Lamberg et al. 2013; Søndergaard et al. 2017). In intraoperative practice, successful outcomes are related to standardised care by adherence to IP guidelines in the sterile operation field. Contrary to the general assumptions, observations in clinical settings have reported infractions in APs (Crown & Greene 1982; Crow & Taylor 1983; Kasal 1985; Liljeblad 1999). Barriers and facilitators for guideline adherence have been reported (e.g., Jun et al. 2016). Cost-effective and efficient IP demands a broad understanding regarding factors related to guideline adherence in interprofessional surgical environments (Cabana et al. 1999; Francke et al. 2008), as well as both technical and non-technical skills (Mitchell et al. 2011 & 2012; Wick et al. 2012). (Table 7, p. 48-49.)

In Finnish OTs, intraoperative AT was evaluated according to the AORN 1991 recommendated practices (Liljeblad 1999). Aseptic infractions were found in all observed operations. The organisation pattern, work experience or education of the OT personnel, the procedure or type of anaesthesia, barrier materials used or the time of operation did not correlate with the aseptic infractions during wound class I and II operations. Most aseptic infractions took place in long operations, lasting more than two hours. In OTs where the traffic during the operation was heavy, the number of aseptic infractions was higher than in operations with moderate traffic. The most important factor correlating with recommended AT was the presence and professional performance of the circulating nurse in the OT during the entire operation.

Several psychological theories are applied to the implementation and evaluation of guideline adherence (e.g., Rosenstock 1974; Seto et al. 1991; Seto 1995; Nesler et al. 1999; Michie et al. 2005). Odgen (2003) reported that there was no consensus regarding the excellence of any of the existing theories in explaining guideline adherence. Varying results have been reported after programmes and projects aiming to improve the adherence of surgical personnel to IC and IP measures.

The effectiveness of educational programmes in the field of occupational IC were often high, from 50% to 75% improvement in the process results, but also the cost of the programmes were high (Roudot-Thoraval et al. 1999). Traditionally, the efficacy of IP and IC programmes is explained by the direct impact of information feedback to the surgical personnel, especially for surgeons (Rioux et al. 2006; Sutherland et al. 2014). Traditional training did not affect the use of double gloves, eye protection or passing sharps through a neutral zone in Welsh OTs (Cutter & Jordan 2012).

The characteristics of professionals, including the awareness of the existence of and familiarity with the content of guidelines, have been reported to affect guideline implementation. Differences between male and female healthcare workers, as well as between nurses and physicians, have been reported to affect guideline adherence. The implementation of clinical guidelines from the bottom up have been reported as successful (Cabana et al. 1999; Francke et al. 2008; Sutherland et al. 2014; Jun et al. 2016).

"Behavioural regulation" has been identified (Michie et al. 2005) as a theoretical domain within which the barriers and facilitators for recommended practices are recognised as individual constructs. Results of Gillespie, Chaboyer and Wallis (2009) indicated that as an individual characteristic, long clinical experience of OT nurses predicted resilience in the workplace, improving stress management. OT nurses with long work experience developed various coping strategies, facilitating adaptation in their current context in which they were frequently exposed to stressful situations when working with demanding and explosive interdisciplinary team members.

The organisation culture was found to be important in guideline adherence (Jun et al. 2016). In Welsh hospitals, surgeons reported less occupational hazards than nurses and midwives (Cutter & Jordan 2004 & 2012). Of 410 Turkish surgical nurses, 50.2% reported non-compliance with protective precautions. Nurses working in OTs had higher scores regarding implementing universal precautions than in other settings (Taze & Cavdar 2016). Several studies have reported surgeons to typically consider sharps injuries as not worth reporting (Becker et al. 1990; Zimakoff et al. 1992; Houang & Hurley 1997). The physicians responsible for the AMP guideline implementation have reported not monitore the guideline adherence among the personnel to whom they delegated the AMP (Sutherland et al. 2014). In the UK, the occupational exposure rates among porters, security and housekeeping staff changed minimally between 2002 and 2011. Most of their exposures were percutaneous, caused by inappropriately discarded needles by others. The exposures were preventable, indicating non-compliance with the safe disposal of clinical waste (Health Protection Agency 2012).

2.4.1 BARRIERS FOR INTRAOPERATIVE ASEPTIC PRACTICES

There are multiple challenges in developing and implementing AP guidelines and recommendations and improving the adherence of surgical personnel to

intraoperative AP (Raven & Haley 1982; Seto 1995; Osborne 2003; Pittet et al. 2003; Gillespie et al. 2009; Efstathiou et al. 2011; Maharaj et al. 2012). The contents of the guidelines or the working settings do not necessarily guarantee adherence to the recommendations (Angelillo et al. 1999; Pittet et al. 2003; Francke et al. 2008; Pan el al. 2009; Cumbler et al. 2013). Even occupational safety guidelines for exposure to blood and body fluids have been compromised (Kretzer & Larson 1998; Stein et al. 2003; Jeong et al. 2008). To facilitate the practical implementation and research of guideline adherence, Cabana and associates (1999) classified their barriers into three categories: barriers affecting knowledge, barriers affecting attitudes and barriers affecting behaviour.

Barriers affecting knowledge

Barriers affecting knowledge include lacking an awareness of or familiarity with the guidelines (Cabana et al. 1999). In an acute care hospital, the self-reported adherence to preventive guidelines correlated with the knowledge of the precautions (Gershon et al. 1999). The effect of the time since a professional was certified on their guideline adherence is unknown (Cutter & Jordan 2004; Francke et al. 2008; Efstathiou et al. 2011).

Lack of knowledge and clarity (Cutter & Jordan 2004), and standardisation in orders (Burkitt et al. 2009), as well as a lack of concise and deliverable policies (Cutter & Jordan 2012), were defined as obstacles to AP guideline adherence. In Iranian hospitals, the most common reasons (20.4%) for non-adherence to local IP protocols were the uncertainty of the protocols (Lakbala et al. 2014). Lack of training was associated with needlestick injuries in Uganda (Nsubuga & Jaakkola 2005). In South Africa, limited knowledge about IP protocols was reported to be related to recent blood and body fluid exposure (Nkoko et al. 2014).

Insufficient strategy implementation, like a lack of training on guidelines (Welc et al. 2013), inexperienced personnel being responsible for guideline adherent practice (Burkitt et al. 2009; Sutherland et al. 2014) and awkward reporting mechanisms (Cutter & Jordan 2004) impeded the guideline adherent AP in surgical environments. The barriers resulting from implementation strategies were related to injury reporting (Burkitt et al. 2009; Cutter & Jordan 2004; Welc et al. 2013).

Barriers affecting attitudes

Barriers affecting attitudes include lacking agreement with guidelines, lack of confidence in the guideline developer or guidelines in general, lack of self-efficacy, lack of outcome expectancy, or lack of motivation to implement the guidelines or considering the status quo adequate (Cabana et al. 1999). Work experience, both long and short, and personal characteristics, as well as the behaviour of surgical team members (Killen 2002; Silén-Lipponen et al. 2004;

Timmons & Tanner 2005; Gillespie et al. 2009), especially the perception of invulnerability among surgeons (Cutter & Jordan 2012), were seen as barriers to AP recommendation adherence. In the OT, environmental characteristics such as a lack of support from peers or superiors and poor communication impeded guideline adherence (Espin & Lingard 2001; Lingard et al. 2002; Flin et al. 2006; Francke et al. 2008; Jun et al. 2016). The self-reported adherence to preventive guidelines correlated with the organisational safety climate and perceived conflict of interest among healthcare workers (Gershon et al. 1999).

Barriers affecting behaviour

Barriers affecting behaviour are often external. External barriers include patient-related factors like infections, guideline factors like the presence of contradictory guidelines, and environmental factors like lack of time or resources. In situations with no barriers affecting a physician's knowledge of or attitudes towards guidelines, external barriers were still found able to affect the ability to execute guidelines (Cabana et al. 1999). Nursing studies support these findings as well (Efstathiou et al. 2011; Sinkowitz-Cochran et al. 2012; Jun et al. 2016).

Among acute care hospital personnel, the self-reported adherence to preventive guidelines correlated with the perception of risk (Gershon et al. 1999). The perception of one's risks, benefits and barriers demonstrated significant but varying correlations with AP adherence of the OT personnel (Osborne 2003).

The characteristics of the patient, like low infection risk (Cutter & Jordan 2004), female gender (Vaisbrud et al. 1999) and challenges like obesity and comorbidities (Francke et al. 2008) have been reported to reduce guideline adherence. Low regional prevalence of acquired immune deficiency syndrome (AIDS) has been related to lower glove-use guideline adherence (Kaczmarek et al. 1991). In the study of Cutter and Jordan (2004), respondents reported modifying their behaviour according to their subjective assessment of a patient's likelihood of having a bloodborne viral infection.

Working conditions and stress was reported to associate with non-adherence to guidelines resulting in infections and occupational injuries. Cypriot OT nurses reported emergencies as barriers to guideline adherence due to limited time (Efstathiou et al. 2011). Long work hours, high work stress, and poor collaboration among the ward staff was associated with HAIs among patients in Finland (Virtanen et al. 2009). Long work hours, work habits and experience were reported predictors for needlestick injuries in Uganda (Nsubuga & Jaakkola 2005). The majority of Cypriot nurses with occupational exposure to pathogens made a report of the incident. The main reasons for not reporting included being too busy and forgetfulness (Efstathiou et al. 2013). In Iranian hospitals, the most common reasons for non-adherence to local IP protocols were prolonged operation or inability to leave the operation table

(17.3%) (Lakbala et al. 2014). These are also common reasons in other healthcare settings (Jun et al. 2016).

The Health Protection Agency (2012) defined healthcare worker-related factors such as distraction, tiredness, inexperience and rushing the procedure as decreasing guideline adherence and increasing the risk for occupational injuries in the UK. Numerous previous studies also reported the association between time and guideline adherence (Espin & Lingard 2001; Lingard et al. 2002; Flin et al. 2006; Francke et al. 2008; Jun et al. 2016).

The lack or non-availability of personal protective equipment and personnel discomfort or dissatisfaction regarding them were practical barriers to guideline adherence (Cabana et al. 1999; Francke et al. 2008; Efstathiou et al. 2011). The major reason (61.6 %) for Turkish surgical nurses' non-adherence to implement protective precautions was the lack of equipment (Taze & Cavdar 2016). The high price of gloves (21.0%) and reduced sensation (21.0%) were the common reasons not to use double surgical gloves in Iran (Lakbala et al. 2014). In a study by Welc and others (2013), negative experiences with using double gloving, having a hands-free zone for handling sharp items during operation or using blunt suture needles were common. Also, skin dryness and irritation decreased guideline adherence (Parienti et al. 2002).

2.4.2 FACILITATORS OF INTRAOPERATIVE ASEPTIC PRACTICE

The challenges in improving adherence to intraoperative AP are global (Osborne 2003; Jeong et al. 2008; Haynes et al. 2009; Pan et al. 2009; Adams et al. 2011; Durando et al. 2012; Maharaj et al. 2012, Sakamoto et al. 2014; Jun et al. 2016) calling for technical and non-technical professional skills (Stein et al. 2003; Mitchell et al. 2011 & 2012; Cutter & Jordan 2012; Welc et al. 2013). Professional competencies are required in assessing the quality of evidence for clinical practice (Francke et al. 2008; Saint et al. 2013), in creating and implementing AP guidelines (EU Council 2009; WHO 2011; Storr et al. 2017) according to integrated evidence, and in reporting the outcome based results (APIC 2012). Francke et al. (2008) reported high guideline adherence depending on the guidelines, professionals, patients and environmental characteristics.

Guideline appearances facilitating adherence

Awareness of guidelines, and belief in the advantages of them facilitated guideline and recommendation adherence (Osborne 2003; Welc et al. 2013). Guidelines that are easy to understand, easy to test, and that do not require specific resources had the best chance of being implemented (Francke et al. 2008). Results of a literature review (Zingg et al. 2015) suggested replacing the formal dissemination of guidelines (not changing behaviour) by evidence-based local team and task-oriented education, including workshops, bedside

training, and simulation using problem-based orientation. The review found it important to focus education on the socialisation process and address barriers to behavioural change in all professional groups. Auditing and timely feedback was found to be beneficial in facilitating the implementation of the IP programmes. The definition and use of an effective strategy was found to be beneficial in targeting individuals in the work situation tackling the environmental, organisational and individual barriers and improving the guideline adherence.

AP protocols implemented in an interdisciplinary way (Alerany et al. 2005) and supported by IC experts (Schelenz et al. 2005) were well adhered to. Implementation of risk-related strategies – focusing on high-risk patients, targeting SSI risk factors and infections identified by local risk assessment – improved guideline adherence (Schelenz et al. 2005).

A regional collaboration reported a tool for quality improvements in surgery (Fung-Kee-Fung et al. 2009). Implementation of a comprehensive, interdisciplinary WHO surgical safety check list according to the surgical patient path was associated with a reduction in surgical complications and mortality in hospitals with a high standard of care (de Vries et al. 2010). Experiences after introducing a bundle of care for patients undergoing colorectal surgery into an Australian hospital was reported modestly successful, even the SSI rates decreased over the 12 months following introduction of the bundle (Bull et al. 2011).

The use of structured processes have been shown to improve personnel adherence to recommended AP (Wick et al. 2012). Monthly group meetings of programme group members and an interdisciplinary team consisting of front-line surgical care providers (surgeons, nurses, technicians, and anaesthesiologists) directly involved in the care of colorectal surgery patients during the Surgical Care Improvement Project. The interventions during the project included the standardisation of skin preparation; administration of preoperative chlorhexidine showers; selective elimination of mechanical bowel preparation; warming of patients in the pre-anaesthesia area; adoption of enhanced sterile techniques for skin and fascial closure; and addressing of previously unrecognised lapses in antibiotic prophylaxis. The outcomes were measured according to standard methods from the Centers for Medicare and Medicaid Services. There was no difference in guideline adherence before and after the intervention. During the 12 months following the intervention, the SSI rates decreased 33.3% (95% CI, 9-58%; $p < 0.05$). Accurate outcomes measurement, support of hospital leadership, and engaged front-line personnel were reported to be required for successful SSI reduction.

Repeated Plan-Do-Study-Act cycles have been shown to significantly improve the adherence to multiple IC measures in peri- and postoperative patient care. Follow-up measurements showed improvement in relapses of non-adherence to multiple IC initiatives in surgical patient care (van Thiel et al. 2006). Improvements were reported in guideline-adherent AMP by using the Toyota Production System (TPS) method in employing an automatic stop

order for appropriate surgical AMP. The stop order was effective in reducing the duration of post-surgical AMP in certain surgical specialties (Burkitt et al. 2009).

A hand rubbing protocol with a less irritating alcohol solution improved surgeons' compliance with the recommended duration of hand hygiene (Parienti et al. 2002). In a comparative study, the alcohol-based hand rub was found to be as good as the traditional surgical hand preparation in reducing SSIs, with the added benefit that the hand rub did not cause irritation to the surgeons' skin (Al-Naami et al. 2009).

Characteristics of professionals facilitating adherence

Significant reduction was found in SSI rates with the assistance of a programme encouraging the acceptance of responsibility for a problem (Schelenz et al 2005). An effective IC programme in acute care hospitals included skilled nursing staff, a dedicated and trained IC physician, and microbiological and data management support (Zingg et al. 2015).

In the management of traditional AMP, certain departments were more prone to ignore it than others (Vaisbrud et al. 1999). No statistically significant differences were reported when comparing surgical AMP before and after implementation of local guidelines and a specific medication set for clean and clean-contaminated surgical procedures (Alerany et al. 2005).

In improving the outcomes of IP, tackling the human factors (Chow and Yang 2005; Sinkowitz-Cochran et al. 2012; Saint et al. 2013), decreasing the harmful effects of the equipment used (Parienti et al. 2002; Osborne 2003; Al-Naami et al. 2009; de Korne et al. 2012), use of technical tools and procedural models (Zanetti et al. 2003; Alerany et al. 2005; van Thiel et al. 2006; Burkitt et al. 2009; Ng & Awad 2015) and understanding individuals' behaviour (Seto et al. 1991; Seto 1995; Schelenz et al. 2005; Michie et al. 2005) are critical.

Characteristics of patients facilitating adherence

In a study of Kaczmarek's group (1991), the overall adherence to national glove-use guidelines was high. It was lower in states with a low AIDS prevalence than in states with a high prevalence. Cutter and Jordan (2004 & 2012) reported the perceptions concerning the patient: lifestyle, sexual orientation, nationality and knowledge of a patient's infection status improving the AP recommendation adherence among nursing personnel.

To tackle the challenges in evaluating the effectiveness of IP and IC programmes, the diversity in patient groups and wards should be controlled. A 5% decrease per year in the SSI rate was reported as the result of an improvement in the quality of care (Couris et al. 2007).

Environmental characteristics for guideline adherence

Zanetti et al. (2003) found positive impact on guideline adherence from an automated intraoperative alarm alerting personnel to re-dose AMP during prolonged cardiac operations. de Korne's study group (2012) completed a massive intervention study to improve the positioning of surgical devices in the clean airflow to protect the sterility of the operation field. The project used experiences from airport logistics. Markings on the OT floor for surgical device positioning according to recommendations improved the AP adherence, securing laminar airflow in the sterile field.

In a Spanish hospital, the volume of total and expensive infectious and toxic/pharmaceutical waste was reduced significantly (6.2%) after training the hospital staff in waste segregation (Mosquera et al. 2014). In the UK, the Health Protection Agency (2012) compared contributory factors for occupational exposure to viral infections. The exposures related to the non-adherence of the proper handling and disposal of clinical waste increased from 54% of exposures in 2005-2007 to 65% in 2008-2011. Over the same time, the procedure-related exposures decreased from 29% to 19%, as did healthcare worker-related exposures (from 17% to 16%). These results indicate a need for improving hospital waste segregation in clinical settings to protect the housekeeping personnel in hospitals.

Table 7 *Characteristics of barriers to and facilitators of intraoperative aseptic practice guideline adherence.*

Characteristics	Barriers:	Facilitators:
Guidelines	Lack of standardization in orders (Burkitt et al. 2009) Lack of clarity (Cutter & Jordan 2012) Concise and deliverability in policies (Cutter & Jordan 2012)	Awareness of guidelines (Welc et al. 2013) Belief in advantages to guideline adherence (Osborne 2003; Welc et al. 2013)
Implementation strategies	Inexperienced personnel in responsible for guideline adherent practice (Burkitt et al. 2009) Cumbersome reporting mechanisms (Cutter & Jordan 2004) Lack of training with guidelines (Welc et al. 2013)	Protocol: - implemented in a multidisciplinary manner (Alerany et al. 2005) - supported by IC experts (Schelenz et al 2005) Practical improvements: - design of integrated AMP-systems (Alerany et al. 2005) - using automatic AMP stop order (Burkitt et al. 2009) - marking OT floor for device positioning (de Korne et al. 2012) Use of structured processes: - TPS methods (Burkitt et al. 2009) - education (Cutter & Jordan 2004) Risk-related strategies: - focusing on high-risk patients (Schelenz et al 2005) - targeting risk factors (Schelenz et al 2005) - SSI identified by local risk assessment (Schelenz et al 2005)
Professionals	Surgeons' perception of invulnerability (Cutter & Jordan 2012) Surgeons not reporting occupational hazards (Cutter & Jordan 2004 and 2012)	
Patients	Patient at low risk for infection (Cutter & Jordan 2004) Female gender of the patient (Vaisbrud et al. 1999)	Perceptions concerning patient: - lifestyle, sexual orientation, nationality (Cutter & Jordan 2004) - knowledge of patient's infection (Cutter & Jordan 2004 and 2012) - suspecting infection in the patient (Cutter & Jordan 2004 and 2012)

Environment	Operation: - lack of or limited operating time (Cutter & Jordan 2004 and 2012) - clean operations (Vaisbrud et al. 1999) - elective operations (Vaisbrud et al. 1999) - infrequently performed operations (Vaisbrud et al. 1999) Equipment: - use of equipment (Burkitt et al. 2009) - condition of equipment (Burkitt et al. 2009) Reliance on protocols and equipment: - paper instead of computer-based records (Burkitt et al. 2009) - lack of faith in the efficacy of equipment (Cutter & Jordan 2012) Unavailability of infection prevention measures (Cutter & Jordan 2004and 2012; Welc et al. 2013) Discomfort due to infection prevention measures: - loss or reduced manual dexterity with DG (Cutter & Jordan 2004 and 2012) - decreased tactile sensation with DG (Welc et al. 2013) - protective eyewear impairing vision (Osborne 2003) - poorly fitting DG causing hand numbness and tingling (Osborne 2003) - DG interfering with duties (Osborne 2003) - hand-rubbing protocol causing skin irritation (Parienti et al. 2002) - HFZ distracting or breaking concentration (Welc et al. 2013) Management support: - lack of management support (Cutter & Jordan 2012) - poor examples set by senior staff (Cutter & Jordan 2012)	Operation: - likelihood of bodily fluid exposure (Cutter & Jordan 2004) - clean and clean-contaminated operation (Vaisbrud et al. 1999) - contaminated operation (Vaisbrud et al. 1999) Equipment or protocol: - protocol reduces skin irritation (Parienti et al. 2002) - advantages to new equipment/protocol over the traditional equipment/protocol (Al-Naami et al. 2009)

AMP = anti-microbial prophylaxis; DG = double gloving; HFZ = hands-free zone; IC = infection control; OT = operating theatre; SSI = surgical site infection; TPS = Toyota Production System.

2.5 LITERATURE BASED INITIAL MODEL FOR INTRAOPERATIVE ASEPTIC PRACTICES

Based on reviewed literature an initial intraoperative AP model (Figure 1) was constructed to facilitate the co-creation of recommended APs with the study hospital OT personnel and to assure the holistic approach in intraoperative APs. Published research articles and recommendations were reviewed several times to find relevant factors in reducing the risks for microbial transmission from patients to personnel and the OT environment, as well as from the personnel and OT environment to the surgical patients. Relevant AORN (1999) recommendations for intraoperational AP were selected and the acceptance of them tested among study and comparison hospital personnel. During the research process, the model was focused on intraoperative APs and the "discharge of the sterile field" –consept changed as "disestablishment of the sterile field".

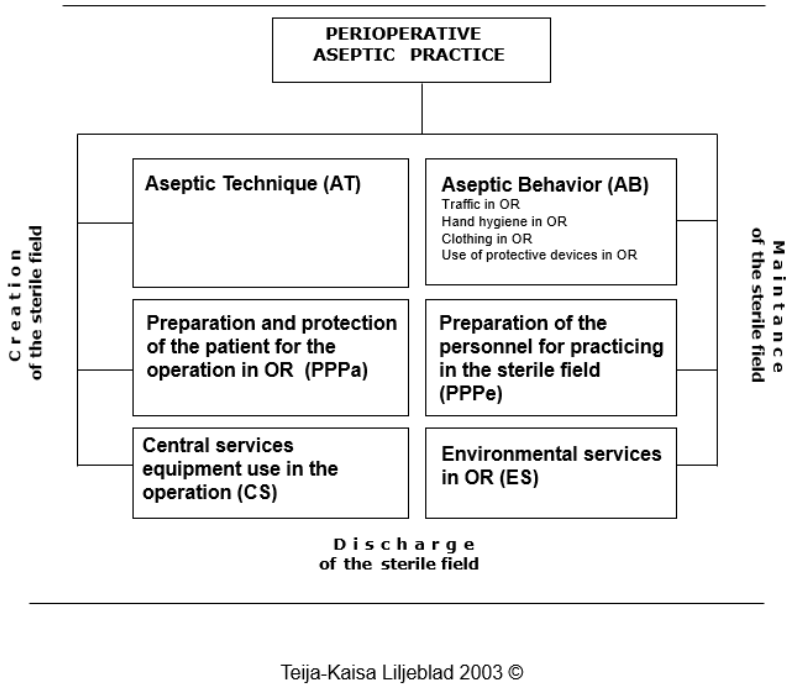

Figure 1 The literature based initial model for intraoperative aseptic practices.

3 AIMS OF THE STUDY

The purpose of this study was to facilitate a developmental evaluation of intraoperative aseptic practices. The aims specified during the project were:

1) to investigate the acceptance of and adherence to aseptic practices among operating theatre personnel before and after documenting the evidence-based intraoperative aseptic practices as well as during the follow-up study;

2) to introduce assessment tools for intraoperative aseptic practice for further development and improvement;

3) to explore the performance of aseptic practice-related clinical situations; and

4) to define risk factors for surgical site infections in breast operations.

4 MATERIALS AND METHODS

Chapter 4 introduces the context, materials and methods completed during this iterative develpmental evaluation sudy in the study and comparison hospitals before and after the co-creation of the AP recommendations.

4.1 DEVELOPMENTAL EVALUATION OF INTRAOPERATIVE ASEPTIC PRACTICES

The judgement for this developmental evaluation study project (Figure 2, P. 53) is based on an evaluation of intraoperative AT in 1996 in the study and comparison hospitals. The researcher (T.-K.A.) applied and tested the AORN 1991 recommended AT practices as part of her pro gradu thesis project (Liljeblad 1997 & 1999). An observation study of clean and clean-contaminated operations (N=32) was completed in the OTs of the central operating departments of the study and comparison hospitals. The AORN (1991) AT recommendations used as assessment criteria for clinical practice were not fully realised in any of 32 operations. The culturally-validated AT recommendations were also applied in other Finnish hospitals (Oinonen 1999) after the author introduced them in several perioperative seminars and conferences. The results served as the baseline for the current study by indicating the need for improving both the current clinical, as well as the knowledge base and education, of the intraoperative AP.

4.2 STUDY DESIGN

The study was completed in the OT departments of Helsinki University Hospital (HUH) in Finland. Peijas Hospital, serving as a study hospital, was responsible for the surgical care of gastrointestinal; gynaecology; urology; vascular; ophthalmology; ear, nose, and throat; and orthopaedic patients of Vantaa, Kerava and Järvenpää cities. In addition to these patient groups, Jorvi Hospital, the comparison hospital, also served general paediatric patients of Espoo, Kauniainen, Siuntio and Kirkkonummi cities. In the first phase of the study, the breast operations were completed in general operating departments of both hospitals. During the follow-up survey, most of the breast patients were operated in same-day surgery services at Jorvi Hospital. In Peijas Hospital, no breast patients were operated on in 2013.

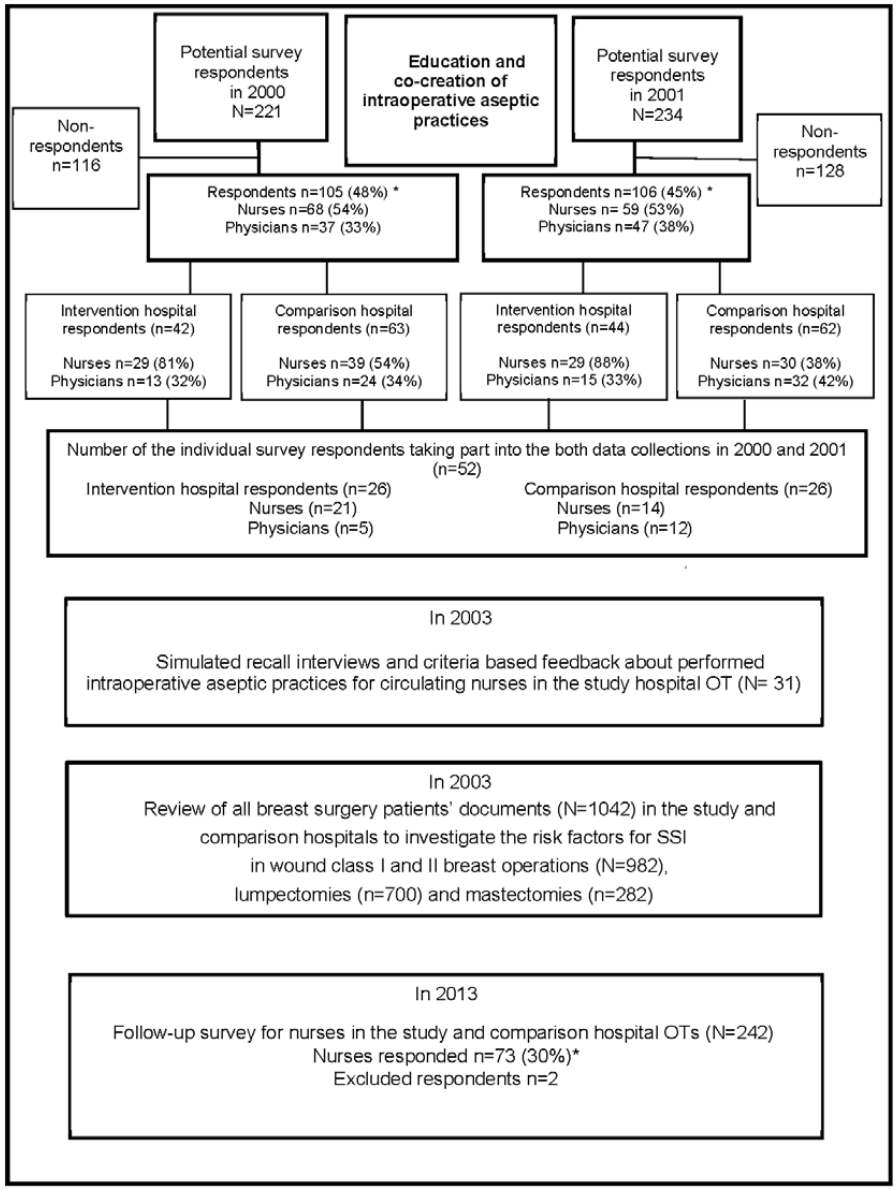

Figure 2 Developmental evaluation of intraoperative aseptic practices.

In Finnish OTs, including in the study and comparison hospitals, perioperative nurses are, in practice, responsible for the APs during operations. The circulating nurse, called the "supervising nurse", usually serves in the named OT as a full member of the surgical team. The supervising nurse starts the establishment of the sterile field by assuring patient positioning and starting the preparations of the patent for the operation by surgical site scrubbing with disinfectant. Immediately after the disinfectant is dried, the scrubbed "instrument nurse" starts the establishment of the sterile operation field by surgical draping, dressing the instrument tables, and preparing and testing the needed equipment and items. The surgeon participates in the establishment of the sterile field mostly by assuring the patient positioning before donning the sterile gown and gloves. Traditionally, the operation starts with the skin incision and ends when the wound is closed. The anaesthesiologists and anaesthesiological nurses participate in the establishment, maintenance and disestablishment of the sterile operation field as surgical team members.

In Finnish hospitals, the medical manager of the surgical units is officially responsible for AP performance and clinical guidance of it. Perioperative nursing professionals are responsible for the intraoperative AP in operating departments. Infection control teams exist in secondary and tertiary care hospitals to guide the operative services. In many hospitals, the responsible nurses lead the continuous clinical development and documentation of ward- and procedure-specific instructions. Those instructions include practical advice for patient and personnel preparation, necessary equipment, environmental requirements as well as overall AB and AT as recommended practices on the ward or during the nominated procedure. In many units, nominated perioperative nurses also follow and mediate the IC reports for surgery personnel. The professional nurses also educate their peers with relevant medical practitioners and IC professionals, nurses and physicians, according to actual needs. The responsible nurses in the study surgery participated in this research project as clinical experts.

According to Finnish legislation, the performance of healthcare services and clinical practices, AP included, are expected to be based on evidence and best professional practices (Health Care Act 1326/2010 & Communicable Diseases Act 1227/2016). Individual healthcare professionals, including nurses, are responsible for providing safe patient care in clinical settings. In Finland, the updated CDC guidelines (Mangram et al. 1999) are implemented in the national guidelines, of which hospitals edit their local versions. Intraoperative AP-related recommendations were also introduced in a guidebook from the national association of Finnish municipalities (Anttila, Hellsten, Rantala, Routamaa, Syrjälä & Vuento 2010) and in the periodicals and websites of the Finnish Society for Hospital Infection Control. The National Institute for Health and Welfare (THL) coordinates the development and surveillance of community- and healthcare-related infections in Finland. It delivers statistical data for research and administrative purposes about

healthcare service use, epidemiological status, and infections. The THL also enables and delivers information about national and international guidelines and recommendations on IC and IP for public and private hospitals via websites and seminars. Participation in the infection surveillance was voluntary until 2017, after which time it became obligatory for public and private service deliverers.

Healthcare service providers are responsible for the continuous education of their personnel. In practice, employers and professionals are together responsible for updating their competence, clinical and theoretical skills, knowledge as well as attitudes towards clinical practices, like AP, according to educational plans. In Finland, organised competence evaluation or continuous education does not relate to the registration of healthcare professionals. AP-related competence testings are rare, even simulation training is part of the clinical workplace education in many hospitals.

Selected universities of applied sciences arrange specialisation studies for nurses in perioperative care, including AP studies. In some universities of applied sciences, there are studies for nurses to improve their competence in IC and IP and certifing as IC nurses. The education takes place in cooperation with the THL. The Finnish Society for Hospital Infection Control delivers continuous interdisciplinary education for professionals in IC and IP.

4.3 METHODOLOGICAL PRINCIPLES

The effort to develop and study the intraoperative AP exposed many practical and methodological biases. The success of previous experimental models testing APs, like hand washing (Larson & Rotter 1990; Loeb et al. 1997) and use of AP equipment (Ransjö & Hambraeus 1979; Moylan et al. 1987; Smith & Nichols 1991; Werner et al. 1991; Flaherty & Wick 1993; Telford & Quebbeman 1993; Hubble et al. 1996; Leonas & Jinkins 1997; Hoborn 2000), were questionable in the clinical evaluation of the intraoperative AP. In clinical impact research both generic and context specific outcome measures focusing on accessibility, quality, equality, effectiveness, safety and efficiency are needed (Malmivaara 2016). The number of variables related to the outcome of AP were high. This is why an evaluative approach and quasi-experimental design (Campbell & Stanley 1963; Shortell & Richardson 1978; Robson 1995) was used in this program (Figure 2, P. 53). In clinical evaluation, only a limited number of the AP-related variables were possible to control, so real-world research was the methodological approach of choice.

The nursing staff of the study OT initiated the co-creation of the local AP recommendations. They intended to improve the quality of intraoperative AP they had worried about earlier in interprofessional teams (Shortell & Richardson 1978). The fundamental elements of the CDC programme (Bolyard et al. 1998) were implemented into the programme. The researcher and OT personnel discussed and formulated the research problem together after evaluating the methods of which the evaluator was responsible. Both

qualitative and quantitative research methods were used. The OT nurses valued the personnel education as an important factor in co-creating clearly-stated written policies, guidelines and procedures ensuring uniformity, efficiency, and effective co-ordination of the local intraoperative APs. The education reflected their work categories (e.g., circulating nurse, instrument nurse, and surgeon) and the varying risk for infections in different roles and procedures during operations. The nursing staff of the study OT selected breast-operated patients as a patient focus group for the AP improvement due to their various intraoperative AP-related challenges in skin disinfection and draping.

An initial model for intraoperative AP (Figure 1, P. 48) was considered important in managing the evaluative development and assuring the holistic approach in AP co-creation. The recommendations and research findings used during the personnel education part of the co-creation of the intraoperative AP were selected and produced according to their appropriateness in content and vocabulary to the (higher) education level, literacy, and language of the personnel (Shortell & Richardson 1978; Bolyard et al. 1998). The evaluation of relevant content and vocabulary started in the survey pilot study, completed in a third operating department of the study hospital district before the first survey.

The survey (III) data was collected according to the study design introduced in Figure 2 (P. 53) in two operating departments of HUH after gaining permission from both study and comparison hospitals. A quality programme with great support from the nursing staff was created in the study hospital after the first data collection. The survey results were used for the cultural validation, testing and co-creation of the local AP recommendations for the interprofessional OT personnel. The AP recommendations were tested in both the study and comparison hospitals before, in 2000, and after, in 2001, the co-creation of the AP recommendations in the winter of 2000-2001. The follow-up survey was completed in both hospitals in 2013. The generalisability of the survey results measuring attitudes, opinions and self-reported APs was not statistical but analytic (Robson 1995).

The co-creation of the AP recommendation with OT staff, completed by the reserarcher followed the existing local and national regulations and requirements for the education of post-degree healthcare workers. The study and education plans and results were introduced to all personnel during their weekly meetings before and after implementation. The education sessions, interactive lectures and workshops, during which the intraoperative AP recommendations were co-created, were completed in the winter of 2000-2001. All physicians and registered nurses working in the main operating department of the study hospital were invited to the development work. Mainly nurses participated in the four AP education and documentation workshops, despite also introducing the study programme to all of the physicians during their weekly meeting. Only the responsible medical manager of the operating units participated in the workshops.

According to Williamson (1978), the characteristics of surgical practices are useful to investigate by observation. In 2003, after the co-creation of the intraoperative AP recommendations, the stimulated recall interview study (I) of the circulating nurses were completed in the study OT. Of the study OT nurses 31 voluntaryly participated in stimulated recall interviews of breast operations. The qualitative study was performed to explore AP-related factors describing and explaining the social conditions during breast operations under which AP, as organisational work, was and not done as recommended in international literature. It sought answers to the questions about the how and why of the organisational outcomes of AP. It revealed the unintended consequences of the co-created AP recommendations. It also contrasted the outside perspective with the inside perspective, focusing on the details of surgery professionals' shared organisational knowledge and their everyday actions and multiprofessional interaction in the intraoperative AP (Miller et al. 2004).

In 2003, a retrospective chart review of 1042 breast operations was completed. Documents before and after the co-creation of AP recommendations was reviewed aiming to assess the improvement in intraoperative AP as outcomes of implementated AP-recommendations. The SSI study group consisted of 982 breast operations, lumpectomies and mastectomies. Contaminated and infected, wound class 3 and 4 opeartions, were excluded.

An approach of technical norms introduced by von Wright (1963) and Niiniluoto (1993; 1996; 2003) was applied as a theoretical framework for the formulation of intraoperative AP recommendations. As technical norms, the intraoperative AP were considered as results of the evaluative development constituting knowledge. The intraoperative APs were defined through the action, skills and concepts of surgical profession(s). The scientification of clinical practice was performed by continuous literature searching and the creation of AP-related evidence. The intraoperative APs were considered as factual statements concerning the relationships between means (APs) and ends (SSIs / adherence to AP recommendations). The recommended intraoperative APs were aiming to provide goals for practical action, expressing professional expertise and facilitating the efficiency of practice.

According to Niiniluoto (1993; 1996; 2003), technical norms, like intraoperative APs, cannot always be deduced from general theory, but they may supported "from below", from clinical performance. The relation to value system of APs varies from a positivist ideal of value-neutral science. As conditional statements, technical norms do not require a commitment to the value premises of their antecedents. They are binding only for those who accept their conditional value premises. APs, like many other professional skills, are developed from cookbook-like orders reasoned by everyday experience towards evidence-based causal order, and technical norms. Figure 3 describes an example of a development of a hand hygiene-related technical norm.

1) An order: “Wash hands!”

2) A relative order: “Wash hands before operation!”

3) Results of causal research findings: “Wash and disinfect hands, because it will help to decrease the amount of wound infection from 39% to 3.2%.”

4) A technical norm: “If the aim of perioperative aseptic practice is to prevent the surgical site of perioperative patient from contamination and to prevent the perioperative personnel from occupational exposure to infections, it is useful / it is necessary to performe preoperative hand wash and disinfection to reduce the resident microbial count of hands to a minimum.”

Figure 3 An evolutional example of technical norm for surgical hand hygiene.

4.4 DATA COLLECTION AND ANALYSIS

This chapter introduces the data collections and analyses in the order of research objectives. The acceptance of and self-reported adherence to intraoperative AP of the OT personnel were investigated by pre- and post-intervention surveys in 2000 and 2001 and a follow-up survey in 2013 (III). The operation-related data were collected from breast operations and patients to assess the SSIs before and after AP co-creation in the study OT (II) in 2003. The stimulated recall interviews were completed after the co-creation of the AP recommendations simultaneously with the register data collection to reveal the challenges in intraoperative AP (I).

4.4.1 MEASURING THE ACCEPTANCE OF AND ADHERENCE TO INTRAOPERATIVE ASEPTIC PRACTICE RECOMMENDATIONS

The original survey questionnaire to measure the acceptance of, adherence to and reasoning for the intraoperative AP recommendations was based on AORN (1999) recommendations, social cognitive theories investigating the guideline adherence and issues found relevant in the context of intraoperative AP during the first observational research in study and comparison hospitals (Liljeblad 1997 & 1999). Of the 120-item hardware questions used in 2000 and 2001, 19 measured background data, 14 the reasoning for APs, 8 exposure to infections, 32 self-reported adherence to APs and 47 acceptance of AP.

The questionnaire was pre-tested among 22 members of non-study OT personnel in the HUH in 2000. Seventeen nurses and physicians answered and assessed the questionnaire, reporting that it was easy to use and the

content of it was valid. Minor improvements were made regarding the wording of the statements after the pilot testing.

The pre-intervention questionnaire was sent in June 2000 to 221 potential respondents (Figure 2, P. 53). The total number of responders after reminding questionnaires was 105 (48%). Of the physicians 33% and of the nurses 54% responded to the questionnaire. The response rate of nurses was better in the study hospital (81%) than in the comparison hospital (54%).

In September 2001, after the co-creation of the intraoperative AP recommendations, 234 questionnaires (identical with the year 2000 questionnaire) were sent, 106 of which were returned. In total, 59 of 111 potential nurse respondents (53%) and 47 of 123 potential physician respondents (38%) returned the questionnaire. The total response rate was 45%. Nurses in the intervention hospital responded more actively (88%) than nurses in the comparison hospital (38%). This project was performed during a period of heavy organisational development in the HUH. Only 52 of 211 respondents, 26 in each hospital, participated in both surveys.

The acceptance of and adherence to intraoperative APs was measured by 79 multi-item Likert-scaled AP statements with a four-point scale (1=strong disagreement / non-adherence, 4=strong agreement / adherence). Both positive and negative statements were used in order to avoid distorted results and to improve the reliability of the data collection. All of the items were coded so that higher numbers represented stronger agreement or self-reported adherence to AP recommendations. Before the co-creation of the AP recommendations, the item-level variation in acceptance of and adherence to the recommendations (*agree* or *strongly agree* in the self-reported adherence) was measured by valid numbers, percents, mean values, and standard deviations (SD). The difference between hospitals was measured by χ^2 tests.

An explorative factor analysis among the relevant statements did not manage to reduce the items to a consistent structure. A content-oriented construction was achieved by grouping the 47 relevant items for Cronbach's alpha scaling according to the three phases of the operation: establishment, maintenance and disestablishment of the sterile field.

Of the 2000 and 2001 data respectively, three summation variables were constructed according to the three phases of AP measures in the sterile field. Altogether, 25 items were comprised the intraoperative AP recommendations for establishing the sterile field scale. The scale measuring the recommended AP for the maintenance of the sterile field included 19 items. Only three items measured the disestablishment of the sterile field.

Two scales, establishment and maintenance of the sterile field, consisted of only items for the acceptance of AP recommendations. The acceptance of and adherence to the intraoperative AP recommendation were both represented in the three-item scale for disestablishment of the sterile operation field (Table 8). At this point, the items were placed so that each item occurred in only one

summation variable to reach the highest possible alpha value. The Cronbach's alpha values for the internal consistencies of the scales were all at good levels.

Table 8 *The three scales measuring intraoperative aseptic practices in 2000 before and in 2001 after the co-creation of the local recommendations.*

Cronbach's alpha (α) value for the scales measuring aseptic practices according to the phases of operation before / after documenting the local recommendations	**Mean / median (SD)** Before documenting the local recommendations (n= number of respondents)	**Mean / median (SD)** After documenting the local recommendations (n= number of respondents)
25-item scale for establishment of the sterile field α=0.750 / 0.766)	3.22 / 3.25 (0.313) (n=105)	3.23 / 3.28 (0.317) (n=105)
19-item scale for maintenance of the sterile field α=0.799 / 0.719	2.87 / 2.89 (0.398) (n=105)	2.98 / 2.95 (0.358) (n=105)
3-item scale for disestablishment of the sterile field α=0.762 / 0.638	2.70 / 3.00 (0.869) (n=105)	2.79 / (0.885) (n=106)

The differences in the mean values for the acceptance of and adherence to the AP recommendations between groups (physicians and nurses, males and females, and study and comparison hospitals) were tested by independent sample t-tests. Levene's test for equality of the variances was applied. Mean values of the three scales were compared among the 52 respondents in the study and comparison hospitals by paired sample t-tests to assess the differences within groups before and after the co-creation of the AP recommendations. Statistical significance was defined at the level $p < 0.05$ (Aholaakko & Metsälä 2018).

4.4.2 CONSTRUCTING TOOLS FOR MEASURING INTRAOPERATIVE ASEPTIC PRACTICES (III)

In the autumn of 2013, a cross-sectional descriptive follow-up survey measuring the acceptance of and self-reported adherence to AP recommendations (III) completed in the study and comparison hospital OTs (Figure 2, P. 53). Due to the researcher's respect of the sterile field the recordings focused better on the work of the circulating nurses than persons working in the sterile field. Both the day surgery and main operating department nurses included in the study group due to the organisational changes. The original questionnaire was updated as an online questionnaire by applying the AORN (2013) recommendations and locally identified critical issues as part of the survey questionnaire. Of the questions 19 measured

background data, 14 the reasoning for APs, 8 exposure to infections, 66 self-reported adherence to APs and 82 acceptance of AP recommendations presented according to phases of operation.

Between October and November 2013, the online surveys were distributed only to OT nurses working in four OT department of HUH. The response rate, among the 242 nurses contacted, was 30% (n=73). After receiving two email reminders and a reminder from their nursing managers, 16 (27%) OT nurses and 10 (21%) day-surgery nurses responded in the study hospital. In the comparison hospital, the response rates of OT nurses were 33 of 95 (31%) and of day-surgery nurses 12 of 40 (30%). Gender was not identified due to the low number of males in the study group (n=14). Thirteen nurses had participated in the 2000 or 2001 surveys, six in the study hospital and seven in the comparison hospital. Two respondents were excluded due to missing information. Missing values in the data were not replaced. Due to the low response rate, valid responses (n=71) were analysed as a pooled study group.

Of the 2013 respondents, 55% were senior nurses with a college-level degree in nursing, while 45% held a bachelor's-level nursing degree. All participants were registered nurses, except three undergraduate bachelor's-level nurses who were graduating students awaiting official registration upon completion of their practical placements. Among all respondents, 45% had worked in operating units for 15 years or more. In terms of their current positions, 40% of respondents had worked in their current unit for less than 5 years, while 21% had worked in their current units for more than 15 years. Of the respondents, 32 (45%) reported exposure to bloodborne infections in their work.

Of the 2013 data, 20 recommendations were used in describing the AP from circulating nurses' points of view (III). First, descriptive statistics completed to summarise the acceptance of the AP recommendations. Second, summated variables according to the phases of the operation were counted. The aim was to construct a clinically-relevant and reliable scale for the intraoperative AP of Circulating Nurses with three sub-scales: Establishment of Sterile Field (10 items); Maintenance of Sterile Field (7 items), and Disestablishment of Sterile Field (3 items). Meaningful constructions with the possibly high alpha (α)-values were selected. The acceptance of AP-recommendations was analysed by Mann-Whitney U-tests to explore the differences in mean value rankings according to the background factors from the skewed data.

Altogether, 97 statements measuring the acceptance of (58 statements) and self-reported adherence to (39 statements) AP recommendations were used in constructing two AP assessment tools for scrub nurses (Aholaakko & Metsälä 2018). First, descriptive statistics of the respondents were computed and two clinically-relevant and reliable scales with high Cronbach α values (0.824 and 0.822) for internal consistency were created. Second, summation variables were computed according to the two scales in order to measure the realisation of the AP recommendations for 1) the scrub nurse preparing to work in the sterile field and for 2) the scrub nurse working in the sterile field. The

differences in skewed background characteristics (education, less or more than 15 years of OT work experience overall and at current OT unit) and exposure to bloodborne infections were tested with Mann-Whitney U-tests (Aholaakko & Metsälä 2018).

4.4.3 OBSERVING THE INTRAOPERATIVE ASEPTIC PRACTICES (I)

The qualitative stimulated recall intervention study was performed to explore AP-related factors describing and explaining the social conditions during breast operations under which AP, as organisational work, was and not done as recommended in international literature. It sought answers to the questions about the how and why of the organisational outcomes of AP. It revealed the unintended consequences of the co-created AP recommendations. It also contrasted the outside perspective with the inside perspective, focusing on the details of surgery professionals' shared organisational knowledge and their everyday actions and multiprofessional interaction in the intraoperative AP (Miller et al. 2004).

The data was collected from February to June 2003 in the OTs of the study hospital (Figure 2, P. 53). Due to the researcher's respect for the sterile field the recordings focused better on the work of the circulating nurses than persons working in the sterile field. The visual data of 3,358 minutes was video-recorded during 31 breast operations (range: 42 to 213 minutes; mean 108 minutes), starting when the nurse created the sterile fields and ended at the disestablishment of the sterile field after the operation. The AP-related feedback and stimulated recall interviews with circulating nurses supervising the AP during the operations were recorded on audiotape as part of clinical education. Of the nurses in the study OT, 31 participated, 2 refused, and 1 was not performing AP supervision during operations. The researcher collected, transcribed, analysed and reported all the video and interview data.

The researcher viewed the complete videos and assessed the performance of AP during breast operations by a semi-structured assessment instrument constructed according to the co-created AP recommendations. The researcher and AP circulating nurses observed and evaluated the AP performance one or two days after videotaping. In the stimulated recall interview, the videotaped operations provided the interviewee with the stimuli of the original situation, improved the reliability of the data collection and constructed a context and situation for clinical education (Jokinen & Pelkonen 1996; Peräkylä 2004). The interviewer supported the interviews with questions like "Please, tell me what is important in AP in this situation?"; "Why did you behave like you did?"; "What are the stress factors of AP during operation?"; "How did you feel? "; and "How did you manage with the stressful situations?"

During the interviews, the nurses self-analysed their AP performance. At the end of the interview, the nurses received criteria-based feedback concerning their AP from the interviewer. The interviewer and circulating nurses together assigned the meaning to the performed AP (Baker 2004).

Twenty-nine of the 31 interviews were technically possible to transcribe. One recording was damaged during storage and one due to a busy clinical situation during the interview. The interview data consisted of 1306 text pages with Ariel 11-point font and single-line spacing. All the authentic expressions were transcribed verbatim. The pauses in interviews were identified by an ellipsis (...). The feelings of interviewees were interpreted and documented in parentheses (e.g., uncertain, frustrated, worried). The noises in surgery during the breast operation made the transcription challenging.

The primary inspection of the text was facilitated by identifying the persons related to the intraoperative AP. AP-related stress was strongly present in the interviews and in the transcribed text. After reading the text, a "membership categorization device analysis of interview talk", introduced by Barker (2004), was applied. The analysed membership categories were used to reveal the routine grounds of the intraoperative AP. The reduced text was analysed by identifying themes and contents. The thematic files were reduced and coded as content classes. In addition, the AP-related clinical assumptions the interviewees expressed were documented.

4.4.4 IDENTIFYING RISK FACTORS FOR SURGICAL SITE INFECTIONS IN BREAST OPERATIONS (II)

The SSIs of breast-operated patients were investigated to identify if there was improvement in SSI rates after the co-creation of the AP recommendations in the study hospital (Figure 2, P. 53). In total, 1042 breast operations were completed in both the study and comparison hospitals from January 1999 to November 2000 (pre-intervention) and from January 2002 to March 2003 (post-intervention). A retrospective chart review of breast surgery patients was completed. The patient files, including all the breast surgery-related documents, were reviewed in the archives of both hospitals. Data was also searched for in the computer-based operation statistics. The data on patient demographics, procedure types, patient and operation-related factors were collected by a 61 item self-administered document. Of the items 13 focused on patient background information, SSI risks and infection status, 7 on pre- and intraoperative preparations and procedures, 3 on hospital stay and 3 on postoperative interventions and complications. Of the operation related items 12 focused on time, type and OT environment. Data on materials used during operation were collected by 10 items. AP related data were collected by 11 items focusing on the sterile barrier materials, use of personal protective equipment, OT traffic and number and presence of personnel in the operation.

The type of surgery was identified by using the name, national identity code, procedure codes and diagnosis of the patient. SSIs that appeared within 30 days of the operation and diagnosed by a physician were recorded according to the CDC definitions (Emori et al. 1991, Crowe & Cooke 1998, Wilson et al. 2004). The IC nurses of both hospitals confirmed the existence of SSIs from the hospital infection registers. They also confirmed unregistered

SSIs from patient charts and data collection forms together with the author at the end of data collection.

Of the reviewed 1042 operations contaminated and infected, wound class 3 and 4 opeartions, were excluded. The study group (n=982) consisted of lumpectomies (n=700) and mastectomies (n=282). The patient- and procedure-related characteristics were used as independent variables to identify SSI risk factors. Breast-operated patients with SSIs were compared with those without SSIs. Univariate odds ratios and separate backward multivariate logistic regression models for all observed operations (n=982), and for lumpectomies (n=700) and mastectomies (n=282), were calculated. Confidence intervals (CI) were calculated to demonstrate the statistical significance of the results. For the logistic regression analyses, the normality of residuals was tested by probability plots. The homoscedasticity of residuals was explored by plotting residuals. Residuals were randomly scattered. The -2 Log Likelihood (-2LL) was used to measure how well the estimated models fit the data. A good model results in a high likelihood of the observed results (Munro 1997).

4.5 ETHICAL ASPECTS

Evaluation of intraoperative APs includes several ethical challenges. First, it is important to keep in mind that evidence regarding intraoperative APs does not cover all the procedures completed during the establishment, maintenance and disestablishment of the sterile operational field. No straightforward causal effect between the presence of SSIs and the overall performance of intraoperative APs has been reported. Reported local infection outbreaks have been proven to be consequences of breaks in asepsis (Mastro et al. 1990; Jarvis et al. 1991; Schaffner & Mishu-Allos 1995; Allen et al. 1997; Kolmos et al. 1998; Bitkover et al. 2000; McNeil et al. 2001; Barbos et al. 2010), but the patient-, disease-, environmental- and personnel-related factors make the comparison in large study groups challenging. Randomised and controlled clinical trials to investigate AP outcomes are not ethically acceptable. There is no return to the times of Lister or Brewer to improve intraoperative AP in the assistance of genuine and simple comparative clinical outcome data.

Ethical challenges in quality improvement

Lilford et al. (2004) recommended that those wishing to improve patient care and not penalise doctors and managers should concentrate on the direct measurements of adherence to clinical and managerial standards. They considered it as a moral premise that the aggregated comparative data used for judgement by external evaluators should be fair. In interpreting the healthcare evaluation process and outcome data, both negative and positive findings are in danger of being misused. Mortality and morbidity rates, SSI

rates for example, are often over-interpreted, resulting in judgement about the underlying quality of the care. Such judgements can translate into performance management strategies used in punishments and rewards. Fear of stigmatisation may also divert attention from genuine improvement towards superficial improvement or gaming. That is why Lilford and others recommend external evaluators not use comparative outcome data to make judgements about the quality of hospital care. This recommendation challenges the use of the SSI rate as a quality-of-care indicator in surgery and intraoperative nursing. The ambiguous and under-investigated relationship between intraoperative AP and SSIs makes it complicated to use in the performance of AP as a quality-of-care indicator too.

In this study, in the context of intraoperative AP, the OT nurses were considered justified stakeholders. Their practical expertise was used in improving the clinical relevance of the developmental evaluation of intraoperative AP. By this, we aimed for the collected data to truly mirror the underlying differences in the AP performance. In avoiding unfair comparisons provoking inappropriate responses, the evaluator performed open, reflective dialogues with the personnel of the study OT. During the evaluations, the competencies and performance were distinguished from each other. This study only evaluates how intraoperative AP was performed in the study OT or self-reported to be performed in the study and comparison OTs, not the competencies of what the OT personnel know and can do under ideal circumstances (Baartman et al. 2007).

Study design-related ethical challenges

At the beginning of this study, it was considered unethical to compare operations implementing AP recommendations with operations not implementing them. In clinical settings, the ethical and practical reasons made it impossible to randomise participants or operations, so the real-world research approach with cross-sectional and quasi-experimental designs (Figure 2, P. 53) was used (Shortell & Richardson 1978; Robson 1995; Newman & Brown 1996; Patton 2011). It was also considered impossible to develop AP by educating part of the personnel in the OT and leave the other part without education.

The educational procedures followed professional practices and the permissions were drafted from relevant bodies in the university hospital district. The ethical board reviewed the study plans and procedures before video recording the operations including patient participation. The anonymity of the patients was carefully secured according to the ethical board review. The faces of the patients were covered in the beginning and during the surgery with the assistance of the nurse anaesthetists (Roudot-Thoraval et al. 1999).

Ethical principles implemented during the study

In this study, the professional ethical codes, like the Helsinki Declaration (World Medical Organization 1996) and Nursing Ethics (ICN 2012), and the best research practices (Sygeplejerskers Sambunde i Norden 1983) guided the entire research process. The AORN (1991 & 1999) recommended practices were considered as technical norms (von Wright 1963; Niiniluoto 1993; 1996; 2003) guiding the developmental evaluation of the clinical APs in study and comparison OTs, increasing the ethical adequacy of the study.

The ethical principles of respecting autonomy, justice, beneficence, non-maleficence (Beauchamp & Childress 2001), equality and integrity, as well as values like safety and sustainability (Newman & Brown 1996), guided the methodological and practical decisions made during this study. According to Newman and Brown (1996), the codes for evaluative research are important to construct responding to the actual situations and settings. Therefore, the implemented ethical codes will demonstrate the interaction between the general ethical principles and theories. In real life, the theories, principles and regulations may challenge each other. In the case where the ethical regulations do not work, the principles may guide the practice.

The principle of autonomy was realised in this study when the informed consent was obtained from the participants (I – III), patients and members of personnel. They were both able to use their own free will in participation or withdrawal. The withdrawal of both patients and members of personnel was few and was respected carefully. The privacy of all stakeholders was protected and the confidentiality of all data and information secured. The patient document data (II) was collected and encoded anonymously in the hospital archive premises. The principle of non-maleficence was implemented in securing the autonomy and safety of the patients and personnel. The details regarding breaks in AP were published after careful reflection (I – III). In addition, negative results were reported but the potential harm due to increased fear concerning surgical procedures or lost personal or public trust was avoided. The stress and reputation-related harm avoided by not personalising the AP adherence during the feedback for circulating nurses (I). At the end of the stimulated recall interviews, the researcher compared the actual and recommended AP, so the interviewee not only got direct feedback about one's practice but also guidance on how to correct it to better meet the documented local AP recommendations. This was considered to be a debriefing of the research participants (Newman & Brown 1996). In the qualitative analyses, the abstraction level of the published results was increased, aiming to protect the integrity of all the stakeholders, patients and professional practitioners.

Competences of the researcher

The requirements for the researcher's, i.e. the evaluator's abilities were reflected in the assistance of the Newman and Brown (1996) criteria. The evaluator should be able to continuously reflect on the harms due to the evaluated practice and lack of it and interfere with the performance when necessary. The principle of non-maleficence was realised through the continuous assessment of the evaluative practice, aiming to cause no harm to the stakeholders. At the beginning of the study, it was decided that the evaluator would interfere in the practice only when there is a risk to lose something, risk for injury or other kind of severe harm. Being external, the evaluator was free from multiple dilemmas an internal evaluator would have had (Beauchamp & Childress 2001; Newman & Brown 1996).

The lack of an evaluator's competence related to the evaluative practices, methods or contents of the evaluation has generally been considered to be heavy ethical misconduct (Newman & Brown 1996). In this study, the evaluator was familiar with the intraoperative AP. She is a perioperative nurse by education. She has observed the AP in the study OTs and other surgical environments since mid-1990 and has long experience in introducing the evaluative procedures and results of evaluative projects both locally and internationally. Since the late 1990s, she has been in charge of the clinical development projects of the nursing students in higher healthcare education. As a member of interprofessional research groups, she has published results in international journals and conferences.

5 RESULTS

Chapter five introduces the results according to the study objectives. First, are reported the acceptance of and adherence to APs among OT personnel before (n=105) and after (n=106) the co-creation of the intraoperative APs. Second, are reported the tools constructed for assessing and improving the intraoperative AP in the roles of circulating (III) and scrubbed team members. Third, are reported the results of the qualitative stimulated recall interviews from 31 circulating nurses revealing AP-related stress (I). Fourth, are reported the rates and risk factors for SSIs in breast operations (II). The original results of the local evaluations comparing the pre- and post-intervention outcomes completed in early 2000 are presented for first time in this report. (Aholaakko & Metsälä 2018). The full results are presented in the original articles, in parentheses the Roman numeral of the article corresponds with those on page 12 of this book.

5.1 ACCEPTANCE OF AND ADHERENCE TO INTRAOPERATIVE ASEPTIC PRACTICE RECOMMENDATIONS

The acceptance of and self-reported adherence to AP recommendations were evaluated by comparing the survey results before (in 2000) and after (in 2001) the co-creation of the intraoperative AP recommendations. The results were reported using scales constructed of the international AP recommendations and needs identified previously in the study and comparison OTs. The structure of the scales followed the three phases of the intraoperative AP: the establishment, maintenance and disestablishment of the sterile field.

5.1.1 ACCEPTANCE OF RECOMMENDATIONS BEFORE AND AFTER RECOMMENDATION CO-CREATION

The acceptance of the recommendations for intraoperative AP were reported with the assistance of three scales (Table 8, P. 58). Two of these scales included statements measuring only the acceptance of the AP recommendations. The third scale, disestablishment of the sterile field, measured both the recommendation acceptance (one item) and self-reported adherence (two items). Only three international recommendations were available.

The statements focused mainly on the intraoperative aseptic technique (AT) and aseptic behaviour (AB). The differences in acceptance of AP recommendations and AP adherence were reported according to background factors and exposure to bloodborne infections (Aholaakko & Metsälä 2018). The scale for the establishment of the sterile field (Table 9) consisted of 25

statements. The scale mean value was reasonable before the AP recommendation co-creation. It increased slightly after the intervention, from 3.22 to 3.28. The most accepted recommendations focused on the safety of the sterile items. The least accepted recommendations by respondents were the seven international recommendations focusing on the

Table 9 Acceptance of the intraoperative aseptic practice recommendations for the establishment of the sterile field.

Recommendations for the establishment of the sterile field before / after co-creation (n=)	**Mean (SD)** before / after co-creation
Most upper packaging removed outside OT (n=98/93)	2.58 (1.266) / 2.95 (1.046)
Sterile barriers made of cotton not safe* (n=102/95)	2.80 (0.975) / 2.80 (0.941)
Sterile field created less than hour before operation* (n=104/99)	3.38 (0.828) / 3.46 (0.644)
Sterile field not created near patient's head (n=89/84)	2.63 (1.142) / 2.69 (1.075)
Sterile field of m^2 is not big enough for any operation* (n=92/93)	3.39 (0.798) / 3.32 (0.899)
Integrity of the package inspected before opening (n=104/104)	3.98 (0.407) / 3.86 (0.598)
Sterile item not used after expiration date (n=104/104)	3.59 (0.705) / 3.46 (0.924)
Sterile items not used if package is opened (n=104/100)	3.62 (0.713) / 3.51 (0.745)
Moisturised sterile package not used (n=103/98)	3.86 (0.444) / 3.85 (0.398)
Damaged sterile package not used (n=103/100)	3.78 (0.463) / 3.66 (0.655)
Sterile item not tossed onto a sterile field (n=104/104)	3.12 (0.900) / 2.98 (0.975)
Sterile gloves not tossed onto a sterile gown package (n=100/99)	3.03 (1.039) / 3.03 (1.073)
Sterile gown not donned in corridor outside OR (n=104/100)	3.44 (0.846) / 3.30 (0.969)
Sterile gloves not donned over main instrument table (n=103/104)	3.65 (0.696) / 3.46 (0.965)
Scrubbed person not tie sterile gown laces oneself (n=102/103)	3.28 (1.028) / 3.31 (1.085)
During draping sterile gloves protected (n= 91/97)	3.24 (1.089) / 3.33 (0.997)
During draping draping material kept compact (n=86/92)	2.13 (0.955) / 2.13 (0.952)
Items over a sterile field covered with sterile barrier (n=101/94)	2.97 (1.081) / 2.97 (1.01)
During draping material kept over waist level (n=99/97)	3.33 (0.857) / 3.45 (0.707)
Suction tubing secured to the sterile field with non-perforating device (n=104/101)	3.5 (0.824) / 3.59 (0.695)
Solution from container opened during previous operation not used (n=103/101)	3.38 (0.865) / 3.38 (0.926)
Solution dispensed from a bottle only once (n=101/99)	2.48 (1.092) / 2.55 (0.982)
Splashes of poured fluid contaminate the sterile field (n=100/98)	2.32 (0.963) / 2.55 (0.975)
Sharps and heavy objects presented onto a sterile field (n=101/96)	3.25 (1.108) / 3.26 (1.069)
Sterile gloves inspected for integrity before operation (n=104/103)	3.86 (0.491) / 3.72 (0.759)
Scale mean (SD) (n=105/105)	3.22 (0.313) / 3.28 (0.317)
Internal consistency of the 25-item scale	α= 0.750 / α=0.766

*) Items converted in 4-point scoring so that higher numbers represent stronger agreement.

aseptic zone-related handling of sterile items before operation, safety of the used materials and securing the operation field by sterile draping. The mean

values for these recommendations all remained lower than the scale mean value.

Table 10 Acceptance of the intraoperative aseptic practices recommendations for the maintenance of the sterile field.

Recommendations for the maintenance of the sterile field* before / after co-creation (n=)	**Mean (SD)** before / after co-creation
Sterile draping not moved to check the electrocautery electrode (n=98/96)	2.77 (0.928) / 2.88 (0.954)
Sterile field not covered during x-ray examination (n=105/101)	1.41 (0.646) / 1.36 (0.626)
Sterile drapes not moved (n=105/100)	3.11 (0.902) / 3.24 (0.965)
Patient's skin re-disinfected if drapes removed during operation (n=99/90)	2.89 (0.46) / 3.0 (0.899)
Both back and front sides of sterile attire not sterile (n=104/103)	3.44 (0.810) / 3.4 (0.943)
Under arms of sterile attire not sterile (n=103/100)	3.15 (1.061) / 3.18 (1.019)
Two scrubbed persons not turn back to face (n=103/101)	2.65 (1.202) / 2.79 (1.259)
Scrubbed person not seated while waiting (n=103/104)	1.77 (0.782) / 1.95 (0.999)
Scrubbed person not keep hands under waist level when seated n=104/105)	3.06 (1.104) / 3.0 (1.092)
Scrubbed person not visit out side OR during operation (n=105/103)	2.7 (0.912) / 2.86 (0.971)
Sterile attire heavily contaminated with blood changed (n=102/99)	2.91 (0.857) / 3.1 (0.827)
Two persons not handle sharps simultaneously (n=100/99)	3.55 (0.744) / 3.67 (0.623)
Intraoperative conversation is aseptically important* (n=104/105)	2.66 (0.888) / 2.75 (0.918)
Number of persons in OR limited during operation (n=104/102)	3.54 (0.723) / 3.65 (0.608)
OR doors kept closed during maintenance of sterile field (n=103/100)	3.35 (0.882) / 3.51 (0.772)
Unscrubbed person not move between two sterile fields (n=103/102)	3.26 (0.885) / 3.39 (0.869)
Circulating nurse not leave OT during operation (n=104/98)	1.66 (0.855) / 1.7 (0.955)
Unscrubbed person keep distance of 50 cm to sterile field (n=105/102)	3.17 (0.935) / 3.41 (0.825)
Defects in aseptic practice are documented (n=104/101)	3.66 (0.495) / 3.72 (0.472)
Scale mean (SD) (n=105/105)	2.87 (0.398) / 2.98 (0.358)
Internal consistency of the 19-item scale	α=0.799 / 0.719

*) Items converted in 4-point scoring so that higher numbers represent stronger agreement.

Nineteen items measured the acceptance of the recommendations for the AP during the maintenance of the sterile field (Table 10). The acceptance varied a lot. The scale mean values improved to some extent (from 2.87 to 2.98), but remained low both before and after the AP recommendation co-creation. The most accepted recommendation focused on documenting the defects in AP. The acceptance of the AB recommendations limiting the number of personnel in the OT during operation and the AT recommendation for the

safe handling of sharps during operation were both respectable. The least accepted recommendation focused on the behaviour of the scrubbed personnel waiting for the operation to start, circulating nurse not dismissing the OT during operation and the covering of the sterile field for X-ray examination.

The acceptance and self-reported adherence to AP recommendations for discharging the sterile field remained low. The mean value for the three-item scale improved to some extent (from 2.70 to 2.79) in the 2001 measurement (Table 11). The recommendation for the safe handling of sharps, not leaving the used needles for colleagues to put away was reported to be well-adhered to. Adherence to the recommendation for the immediate disinfection of blood spills was below the scale mean. The OT personnel reported rather low acceptance of the recommendation for hand disinfection after glove removal.

Table 11 *Acceptance of the intraoperative aseptic practice recommendations for the disestablishment of the sterile field.*

Recommendations for the disestablishment of the sterile field before / after co-creation (n=)	**Mean (SD)** before / after co-creation
Hands disinfected after removing gloves (n=105/101)	2.41 (1.016) / 2.67 (1.031)
Used needles not left to colleagues to put away (n=105/102)**	3.23 (1.161) / 3.1 (1.255)
Blood spills disinfected immediately (n=101/98)*	2.50 (0.945 / 2.67 (1.003)
Scale mean (n=105/106)	2.70 (0.869) / 2.79 (0.885)
Internal consistency of the 3-item scale	α= 0.762 / α= 0.638

*) Asked as self-reported adherence to recommendations

5.1.2 DIFFERENCES IN ACCEPTANCE OF RECOMMENDATIONS

The differences the in acceptance of the intraoperative AP recommendations were identified before and after the co-creation of the local AP recommendations in the study hospital (Aholaakko & Metsälä 2018). Statistically significant differences were found between groups (physicians and nurses, male and female respondents and study and comparison hospitals) according to the three phases of the intraoperative AP in all measurements except the 2000 during disestablishment of the sterile field (Table 12).

Among all the respondents, the nurses accepted the recommendations more than the physicians did in both measurements. The difference was statistically significant in all three AP-related phases of the operation. The difference between male and female respondents was also statistically significant. The differences between hospitals was reported statistically significant in the two phases of intraoperative AP. The recommendations for the establishment and maintenance of the sterile field were accepted and adhered to more than for the disestablishment of the sterile field. The higher acceptance and adherence was reported during the discharge of the sterile field

in the study compared to comparison hospital in both measurements. In 2000, the difference was not statistically significant, but it was in 2001.

Table 12 *Differences in acceptance of aseptic practice recommendations in the study and comparison hospitals according to the aseptic phases of the operation.*

Acceptance of the aseptic practice recommendations before / after co-creation (n=)	**Mean (SD)** before / after co-creation	**t-test (p=)** before / after co-creation
Between physicians and nurses		
Establishment of the sterile field		
2000 (n=37/67)	3.09 (0.34) / 3.31 (0.27)	-3.56 (p=0.001)
2001 (n=47/58)	3.10 (0.32) / 3.34 (0.27)	-3.96 (p=0.000)
Maintenance of the sterile field		
2000 (n=37/67)	2.75 (0.38) /2.94 (0.39)	-2.35 (p=0.020)
2001 (n=47/58)	2.80 (0.31) / 3.11 0.34)	-4.67 (p=0.000)
Disestablishment of the sterile field		
2000 (n=37/67)	1.8 (0.81) / 3.20 (0.37)	-9.83 (p=0.000)*
2001 (n=47/59)	2.11 (0. 86) / 3.33 (0.41)	-8.95 (p=0.000)
Between males and females		
Establishment of the sterile field		
2000 (n=19/86)	3.05 (0.35) / 3.28 (0.29)	-2.90 (p=0.005)
2001 (n=26/79)	3.04 (0.33) / 3.30 (0.29)	-3.86 (p=0.000)
Maintenance of the sterile field		
2000 (n=19/85)	2.67 (0.44) / 2.91 (0.38)	-2.46 (p=0.015)
2001 (n=26/79)	2.80 (0.34) / 3.01 (0.35)	-2.83 (p=0.006)
Disestablishment of the sterile field		
2000 (n=19/86)	1.66 (0.72) /2.93 (0.72)	-7.31 (p=0.000)
2001 (n=26/80)	2.10 (0.86) / 3.03 (0.76)	-5.43 (p=0.000)
Between hospitals		
Establishment of the sterile field		
2000 (n=42/63)	3.30 (0.31) / 3.18 (0.32)	2.08 (p=0.040)
2001 (n=44/61)	3.38 (0.27) / 3.12 (0.30)	4.53 (p=0.000)
Maintenance of the sterile field		
2000 (n=42/63)	3.05 (0.38) / 2.75 (0.36)	4.02 (p=0.000)
2001 (n=44/61)	3.11 (0.37) / 2.88 (0.31)	3.37 (p=0.000)
Disestablishment of the sterile field		
2000 (n=42/63)	2.90 (0.78) / 2.58 (0.90)	1.92 (p=0.058) NS**
2001 (n= 44/62)	3.00 (0.74) / 2.64 (0.95)	2.17 (p=0.032)

*Equal variances not assumed; ** NS = statistically not significant

Paired sample t-tests were conducted among 52 respondents, 26 in each hospital, participating in both the 2000 and 2001 surveys. Mean values for the three scales were compared to assess the differences in before and after the local AP recommendation documentation. In the study hospital, the

recommendation acceptance (and adherence) was found higher than in the comparison hospital within all three scales (Table 13). No statistically significant differences existed.

Table 13 Differences in acceptance of aseptic practice recommendations in the study and comparison hospitals.

Acceptance of aseptic practice recommendations before / after co-creation (n=)	**Mean (SD)** before / after co-creation	**t-test (p=)** before / after co-creation
Establishment of the sterile field		
Study hospital in 2000 / in 2001 (n=26/26)	3.28 (0.31) / 3.28 (0.30)	0.037 (NS)
Comparison hospital in 2000 / in 2001 (n=26/26)	3.04 (0.33) / 3.07 (0.32)	-0.494 (NS)
Maintenance of the sterile field		
Study hospital in 2000 / in 2001 (n=26/26)	3.15 (0.42) / 3.15 (0.42)	-0.486 (NS)
Comparison hospital in 2000 / in 2001 (n=26/26)	2.74 (0.36) / 2.76 (0.28)	-0.347 (NS)
Disestablishment of the sterile field		
Intervention hospital in 2000 / in 2001 (n=26/26)	2.96 (0.72) / 2.98 (0.73)	-0.250 (NS)
Comparison hospital in 2000 / in 2001 (n=26/26)	2.46 (1.0) / 2.50 (0.94)	-0.452 (NS)

NS = statistically not significant

5.1.3 SELF-REPORTED ADHERENCE TO RECOMMENDATIONS

The self-reported adherence to recommendations for hand hygiene and use of surgical attire was measured intraoperative AB. The recommendation level results before and after the local recommendation documentation are introduced in Table 11 and Table 14. In 2000, before co-creating the AP recommendations, the self-reported adherences to AB recommendations assessed at the recommendation level were measured and compared between hospitals by χ^2 tests (Aholaakko & Metsälä 2018).

No statistically significant difference was found between hospitals, with 66% self-reporting adherence to recommendations for hand washing when arriving to the operating department. The self-reported adherence was more common among nurses in the comparison hospital compared to the study hospital (χ^2=10.38, p=0.016). The overall adherence to the recommendation for using hand disinfectant before entering the operating department was 70%. The adherence was statistically significantly higher in the study than in the comparison hospital (χ^2=13.22, p=0.004). In 2000, 33% of physicians in the comparison hospital reported never disinfecting their hands when arriving to the operating department. Of nurses, 82% in the study hospital did so. Overall adherence to the recommendation for using disinfectant before entering a storage room for sterile items was 42%. It was higher in the study than in the comparison hospital. The difference was statistically significant (χ^2=9.932, p=0.019).

In 2000, the overall adherence to hand washing before a new patient was 80%. To hand disinfection, it was 94%. The adherence to hand disinfection,

but not to hand washing, varied, with higher levels in the comparison hospital. The difference was statistically significant (χ^2=8.58, p=0.035). Nurses in the comparison hospital reported the most frequent adherence (78%). In total, 82% of nurses and 85% of physicians in the study hospital, and 74% of nurses and 54% of physicians in comparison hospital, reported disinfect their hands before a new patient.

The total adherence rate to the recommendation for not using a wristwatch in the OT was 90%. Nurses in the study hospital reported 100% and in the comparison hospital 72% adherence. The difference was statistically significant (χ^2=9.44, p=0.024). Between physicians, no difference was reported in the 83% total adherence rate. Among all respondents, the self-reported adherence to not using nail polish in the OT was 97%. The difference between hospitals was statistically significant (χ^2=8.08, p=0.044).

The adherence to the AB recommendation for changing the OT attire daily was high, 96%. The recommendation for wearing a cover gown outside the operation department was more highly adhered to in the study than in the comparison hospital (χ^2=44.27, p=0.000). In the study hospital 88%, and in the comparison hospital 64%, of personnel reported using it. In the study hospital 92% of nurses, and in the comparison hospital 87% of nurses, reported adherence. The difference between nurses in the two hospitals was highly significant (χ^2=56.99, p=0.000).

The majority, 81% of the study hospital respondents, reported always using a haircover covering all the hair. The difference between hospitals was statistically significant (χ^2=9.33, p=0.025). The recommendation for advising visitors to use a cover gown in the OT was better agreed upon in the study than in the comparison hospital (χ^2=8.65, p=0.034), where 48% of the nurses reported always doing so. In the comparison hospital, the recommendation for using protective eyewear (χ^2=9.17, p=0.027) and the recommendation to change one's moist mask (χ^2=10.61, p=0.014) were better adhered to than in the study hospital. Of the physicians in the study hospital, 31% reported changing their moist mask. In the study hospital, personnel reported eating or drinking more often in the OT during long operations than in the comparison hospital (χ^2=10.19, p=0.017). Of the nurses, 67% in the comparison hospital reported not doing so. Wide deviation also existed in adherence to recommendations for handling sharps and reporting infectious diseases to the employer.

Differences between background factors in 32 items measuring the adherence to AB in 2000 were computed. The difference between nurses and physicians was statistically significant (χ^2=63.27, p=0.000, n=104). The adherence to the recommendations for avoiding hazards with sharps by not passing a scalpel from hand to hand (χ^2=8.1, p=0.044) and not recapping used needles (χ^2=9.65, p=0.022) were higher in the comparison hospital. Most nurses (68%) and some physicians (17%) in the study hospital reported always recapping needles.

5.1.4 SELF-REPORTED ADHERENCE TO RECOMMENDATIONS BY ROUTES OF CONTAMINATION

The self-reported adherence to AP recommendations was measured before (n=105) and after (n=106) documentation of the local recommendations. Table 14 introduces the three scales with varying internal reliability constructed according to the routes of contamination (Aholaakko & Metsälä 2018).

Table 14 *Self-reported adherence to recommendations for aseptic behavior by routes of contamination.*

Recommended intraoperative aseptic practice[1)] before / after co-creation (n=)	**Mean (SD)** before / after co-creation (n=)
1) Preventing hand borne contamination by	
washing hands in arriving operating department	3.2 (0.96) / 3.3 (0.82)
disinfecting hands in arriving operating department	3.1 (1.06) / 3.3 (0.85)
washing hands before care of a new patient	3.4 (0.83) / 3.5 (0.87)
disinfecting hands before care of new patient	3.7 (0.58) / 3.7 (0.67)
disinfecting hands outside sterile storeroom	2.3 (0.91) / 2.4 (0.98)
not using nail polish in operating theatre	3.7 (0.58) / 3.7 (0.63)
not using wrist watch in operating theatre	3.7 (0.80) / 3.8 (0.56)
not using rings in operating theatre	3.8 (0.64) / 3.9 (0.46)
Scale reliability α =0.66 / α =0.59	
2) Preventing airborne contamination by	
using all hair covering hair cover	3.6 (0.63) / 3.7 (0.60)
wearing mask when disinfecting operating site	3.4 (0.62) / 3.5 (0.66)
wearing mask when creating sterile field	3.5 (0.60) / 3.5 (0.64)
changing the moistened mask	2.2 (1.03) / 2.4 (1.06)
using cover gown with hepatitis-patient	2.5 (1.19) / 2.8 (1.14)
using cover gown outside operating department	2.7 (1.43) / 2.8 (1.32)
not using lip palm or lipstick in operating theatre	3.6 (0.64) / 3.7 (0.66)
cutting finger nails under running water	1.5 (0.95) / 1.8 (1.04)
limiting discussion during operation	2.0 (0.72) / 2.2 (0.76)
guiding visitor to use surgical attire properly	2.6 (1.13) / 2.7 (1.10)
Scale reliability α =0.58 / α=0.62	
3) Preventing blood borne contamination by	
not leaving used needle for others to take care of	3.2 (1.16) / 3.1 (1.25)
immediate spill disinfection from surgery surfaces	2.5 (0.94) / 1.63 (0.48)
handling patient's specimen as infected material	3.5 (0.73) / 3.5 (0.83)
Scale reliability α=0.82 / 0.78	

1) Items converted in 4-point scoring so that higher numbers represent stronger compliance.

The acceptance of the recommendations for prevention of handborne contamination was measured by an eight-item scale. The recommendations

focused on intraoperative AB. The self-reported adherence to disinfecting hands outside the storeroom was the lowest.

The adherence to recommendations preventing airborne contamination measured by a ten-item scale also focused on AB. The adherence to recommendations for focusing on the use of personal protective equipment (surgical mask and cover gowns), cutting fingernails under running water and limiting discussion during operation were lowest.

The self-reported adherence to all recommendations for preventing bloodborne contamination was high. The internal reliability of the three-item scale recommending the prevention of bloodborne contamination was the highest of the three scales.

Table 15 *Self-reported adherence to recommendations for preventing hand borne contamination.*

Self-reported adherence to recommendations for preventing hand borne contamination			
	Mean (SD) (n=)	**Mean (SD)** (n=)	**t-test** (p=)
Between hospitals	Study	Comparison	
2000 all respondents (n=105)	3.5 (0.35) (n=42)	3.3 (0.47) (n=63)	2.51 (0.014)[1]
2001 all respondents (n=106)	3.6 (0.29) (n=44)	3.4 (0.38) (n=62)	3.17 (0.002)[1]
2000 follow up groups (n=52)	2.9 (0.34) (n=26)	2.6 (0.42) (n=26)	2.41 (0.020)[1]
2001 follow up groups (n=52)	2.9 (0.41) (n=26)	2.7 (0.39) (n=26)	2.20 (0.032)[1]
Between professions	Nurses	Physicians	
2000 all respondents (n=105)	3.4 (0.34) (n=68)	3.2 (0.54) (n=37)	2.18 (0.033)[2]
2001 all respondents (n=106)	3.6 (0.30) (n=59)	3.3 (0.40) (n=47)	3.38 (0.001)[1]
Between genders	Males	Females	
2000 all respondents (n=105)	3.2 (0.38) (n=19)	3.4 (0.44) (n=85)	-1.91 (NS)[1]
2001 all respondents (n=106)	3.3 (0.35) (n=26)	3.5 (0.36) (n=80)	-2.17 (0.032)[1]
Between measurements	Before	After	
Follow up group in the study hospital (n=26)	2.9 (0.34) (n=26)	2.9 (0.38) (n=26)	-0.31 (NS)[3]
Nurses	2.9 (0.32) (n=21)	3.0 (0.37) (n=21)	-1.11 (NS)[3]
Physicians	2.8 (0.39) (n=5)	2.6 (0.47) (n=5)	0.97 (NS)[3]
Follow up group in the comparison hospital (n=26)	2.6 (0.42)	2.7 (0.37)	-1.79 (NS)[3]
Nurses	2.8 (0.29) (n=14)	2.9 (0.21) (n=14)	-2.48 (0.028)[3]
Physicians	2.5 (0.79) (n=12)	2.5 (0.59) (n=12)	-0.44 (NS)[3]

[1] Independent sample t-test with equal variances; [2] Independent sample t-test with unequal variances; [3] Paired sample t-test

The self-reported adherence to recommendations for preventing hand contamination (Table 15) varied significantly between hospitals, both in 2000 and in 2001 among all respondents and among the respondents who participated in both measurements. The adherence was reported higher

among the study hospital groups. The differences were statistically significant. Nurses reported statistically significantly higher adherence than physicians in both measurements. Between males and females, no statistically significant differences for preventing hand contamination were reported in 2000. Females reported significantly higher adherence after the AP recommendation co-creation than males in 2001. Between measurements, the only statistically significant improvement in preventing handborne contamination was among the 14 study hospital nurses participating in both measurements.

Table 16 *Self-reported adherence to recommendations for preventing airborne contamination.*

Self-reported adherence to recommendations for preventing airborne contamination			
	Mean (SD) (n=)	**Mean (SD)** (n=)	**t-test** (p=)
Between hospitals	Study	Comparison	
2000 all respondents (n=105)	2.9 (0.39) (n=42)	2.7 (0.42) (n=63)	3.21 (0.002)[1]
2001 all respondents (n=106)	3.1 (0.39) (n=44)	2.8 (0.41) (n=62)	4.75 (0.000)[1]
2000 follow up groups (n=52)	2.9 (0.43) (n=26)	2.7 (0.45) (n=26)	2.04 (0.046) [1]
2001 follow up groups (n=52)	3.1 (0.36) (n=26)	2.7 (0.37) (n=26)	4.01 (0.000)[1]
Between professions	Nurses	Physicians	
2000 all respondents (n=105)	2.7 (0.43) (n=68)	2.9 (0.43) (n=37)	-1.39 (NS)[1]
2001 all respondents (n=106)	2.9 (0.45) (n=59)	3.0 (0.43) (n=47)	-0.73 (NS)[1]
Between genders	Males	Females	
2000 all respondents (n=105)	2.7 (0.51) (n=19)	2.8 (0.41) (n=85)	-0.37 (NS)[1]
2001 all respondents (n=106)	3.1 (0.42) (n=26)	2.9 (0.44) (n=80)	1.87 (0.64)[1]
Between measurements	Before	After	
Follow up group in the study hospital (n=26)	2.9 (0.43)	3.1 (0.36)	-1.92 (NS)[2]
Nurses	2.9 (0.41) (n=21)	3.1 (0.32) (n=21)	-1.78 (NS)[2]
Physicians	2.9 (0.56) (n=5)	3.0 (.53) (n=5)	-1.18 (NS)[2]
Follow up group in the comparison hospital (n=26)	2.7 (0.45)	2.7 (0.37)	0.16 (NS)[2]
Nurses	2.6 (0.43) (n=14)	2.6 (0.42) (n=14)	-0.73 (NS)[2]
Physicians	2.8 (0.45) (n=12)	2.7 (0.32) (n=12)	1.23 (NS)[2]

[1] Independent sample t-test with equal variances assumed; [2] Paired sample t-test

Self-reported adherence to preventing airborne contamination (Table 16) was reported higher in the study than in the comparison hospital in both 2000 and 2001 measurements among all respondents and those participating in both surveys. The differences were all statistically significant. Physicians reported higher adherence to recommendations for preventing airborne contamination than nurses in both measurements did. The differences were not statistically significant, however. In 2000, no statistically significant

differences were found between male and female respondents in adherence to prevent airborne contamination. In 2001, the male respondents reported significantly higher adherence than females. No statistically significant improvement in adherence was measured among those who participated in both measurements in study or comparison hospitals.

Table 17 *Self-reported adherence to recommendations for preventing blood borne contamination.*

Self-reported adherence to recommendations for preventing of blood borne contamination			
	Mean (SD) (n=)	**Mean (SD)** (n=)	**t-test (p=)**
Between hospitals	Study	Comparison	
2000 all respondents (n=105)	3.2 (0.65) (n=42)	2.9 (0.83) (n=63)	1.49 (NS)[1]
2001 all respondents (n=106)	3.2 (0.65) (n=44)	3.0 (0.83) (n=62)	1.49 (NS) [2]
2000 follow up groups (n=52)	3.3 (0.60) (n=26)	2.8 (0.95) (n=26)	2.15 (0.037)[2]
2001 follow up groups (n=52)	3.3 (0.71) (n=26)	2.7 (0.87) (n=26)	2.50 (0.015)[1]
Between professions	Nurses	Physicians	
2000 all respondents (n=105)	3.4 (0.32) (n=68)	2.3 (0.82) (n=37)	8.04 (0.000)[2]
2001 all respondents (n=106)	3.5 (0.42) (n=59)	2.6 (0.88) (n=47)	6.39 (0.000)[2]
Between genders	Males	Females	
2000 all respondents (n=105)	2.2 (0.87) (n=19)	3.3 (0.58) (n=85)	-5.27 (0.000)[2]
2001 all respondents (n=106)	2.6 (0.86) (n=26)	3.2 (0.71) (n=80)	-3.55 (0.001)[1]
Between measurements	Before	After	
Follow up group in the study hospital (n=26)	3.3 (0.60)	3.3 (0.71) (n=26)	0.23 (NS)[3]
Nurses	3.5 (0.33) (n=21)	3.5 (0.43) (n=21)	0.36 (NS)[3]
Physicians	2.5 (0.89) (n=5)	2.5 (1.19) (n=5)	0.29 (NS)[3]
Follow up group in the comparison hospital (n=26)	2.8 (0.95)	2.8 (0.87)	0.43 (NS)[3]
Nurses	3.5 (0.31) (n=14)	3.4 (0.52) (n=14)	0.81 (NS)[3]
Physicians	2.0 (0.79) (n=12)	2.0 (0.59) (n=12)	-0.27 (NS)[3]

[1] Independent sample t-test with equal variances; [2] Independent sample t-test with unequal variances; [3] Paired sample t-test

No statistically significant differences were found in the self-reported adherence to recommendations for preventing bloodborne contamination (Table 17) between hospitals in 2000 or 2001. The adherence was reported as significantly higher among the study hospital respondents participating in both measurements. Nurses reported their adherence to recommendations significantly higher than physicians, both in 2000 and in 2001. Female respondents reported significantly higher adherence to prevent bloodborne contamination than males did, both in 2000 and 2001. No statistically

significant improvement in adherence was found among those who participated in both measurements in study or comparison hospitals.

5.1.5 EXPOSURE TO BLOOD BORNE INFECTIONS AND ADHERENCE TO RECOMMENDATIONS

The findings, according to which female respondents reported significantly higher adherence to prevent bloodborne contamination than males, guided the closer inspection of the association between the exposure to bloodborne infections and AP adherence (Aholaakko & Metsälä 2018). There was no statistically significant variation in exposure to bloodborne infections among OT personnel in study and comparison hospitals. No exposure to bloodborne infections were reported in 2000. In 2001, about 50% and in 2013 about 45% of the personnel reported exposure in OTs of both hospitals. The most common reasons for the exposure were needlestick injuries and blood spills into eyes or mucosal membranes (Table 18).

Table 18 *Exposure to blood borne infections among respondents in the study and comparison hospitals.*

Exposure to blood borne infections among respondents	Study hospital	Comparison hospital	Difference between hospitals χ^2 (p=)
Exposure to blood borne infections			
in 2000 (n=104)	0 (0 %)	0 (0%)	-
in 2001 (n=103)	23 (53.5%)	31 (51.7%)	NS
in 2013 (n=70)	12 (46.2%)	20 (45.5%)	NS
Blood spills into eyes or mucosal membranes			
in 2000 (n=104)	22 (52.4%)	28 (45.2%)	NS
in 2001 (n=104)	24 (54.5%)	34 (56.7%)	NS
in2013 (n=70)	6 (23.1%)	12 (27,3%)	NS
Needlestick injury			
in 2000 (n=104)	30 (71.4%)	44 (71%)	NS
in 2001 (n=103)	31 (72.1%)	40 (66.7%)	NS
in 2013 (n=70)	26 (46.2%)	23 (52.3%)	NS
Scalpel injury			
in 2000 (n=104)	13 (31%)	14 (22.6%)	NS
in 2001 (n=104)	13 (29.5%)	21 (35%)	NS
in 2013 (n=70)	4 (15.4%)	10 (22.7%)	NS
Skin scratch caused by used drill			
in 2000 (n=104)	2 (4.8%)	4 (6.5%)	NS
in 2001 (n=104)	2 (4.5%)	3 (5.0%)	NS
in 2013 (n=70)	1 (3.8%)	2 (4.5%)	NS
Scratch caused by used wire			
in 2000 (n=104)	3 (7.1%)	3 (4.8%)	NS
in 2001 (n=104)	3 (6.8%)	6 (10%)	NS
in 2013 (n=70)	0 (0%)	1 (2.3%)	NS

In 2001, no statistically significant difference was found in the adherence to hand contamination, air- or bloodborne infections between those exposed to bloodborne infections and those not exposed. The self-reported adherence to recommendations for preventing bloodborne infections was higher among those not reporting needlestick injuries by a used needle (mean=3.41) than among those reporting a needlestick (mean=2.94). The difference, measured

by an independent sample t-test with unequal variances, was statistically significant (t=3.333, p=0.001). No statistically significant differences were found in the adherence to for hand- and airborne infection prevention.

Table 19 Documenting and changing practices after exposure to blood borne infections.

Occurrence of blood borne exposure and related behavior	**Study hospital** (n=42)	**Comparison hospital** (n=62)	**Differences between hospitals** χ^2 (p=)
Documentation of blood borne exposure			
in 2000 (n=100)	26 (65%)	35 (58.3%)	NS
in 2001 (n=98)	33 (82.5%)	35 (60.3%)	5.47 (p=0.026)
in 2013 (n=70)	21 (80.8%)	35 (79.5%)	NS
Changing practices after exposure			
in 2000 (n=90)	18 (48.6%)	12 (22.6%)	6.63 (p=0.013)
in 2001 (n=94)	19 (50%)	20 (35.7%)	NS
in 2013 (n=66)	10 (38.5%)	21 (52.5%)	NS

The documentation of exposure to bloodborne infections was quite similar in both study and comparison hospital OTs in 2000. More than half of the respondents reported documenting their exposures. In 2001, after co-creation of the AP recommendations in the study hospital, the rate of respondents documenting their exposures increased in both hospitals, more in the study hospital however. The difference was statistically significant.

In 2000, respondents in the study hospital OT reported changing their practices after exposure more often than respondents in the comparison hospital OT. The difference was statistically significant (Table 19).

5.2 TOOLS FOR ROLE-RELATED ASEPTIC PRACTICES

This chapter introduces tools for assessing and improving the intraoperative AP in the roles of circulating (III) nurses and scrubbed OT nurses. Due to the limited number of respondents (N=73) in the follow-up survey in 2013, four role-related sets of intraoperative AP recommendations were tested. Three scales for scrubbed nurse will be introduced (Aholaakko & Metsälä 2018).

5.2.1 A TOOL FOR CIRCULATING NURSES' ASEPTIC PRACTICES (III)

Table 20 introduces the mean values of the recommendations and the internal consistency of the 20-item scale recommending the 20-item scale recommending the intraoperative AP for circulating nurses according to the three phases of intraoperative AP in 2013. The recommendation for defining

Table 20 *Intraopertive aseptic practices of circulating nurses.*

In 2013 recommended Aseptic Practices (n=68)	Mean (SD) *
Establishment of the sterile field α=0.605	
Sterile indicators inspected before use	3.95 (0.278)
Indicator gloves taken for risk-operations	3.95 (0.213)
Not using sterile item after expiration date	3.94 (0.244)
Integrity of package inspected	3.89 (0.403)
Fluid transparency inspected before use	3.89 (0.362)
Not using moisturized sterile package*	3.86 (0.467)
Not using opened sterile package*	3.73 (0.623)
Fluids and medicines decanted near use	3.67 (0.714)
Filter needle used with liquids	3.61 (0.748)
Sterile field created less than an hour before operation	3.23 (1.046)
Maintenance of the sterile field α=0.639	
Sterile field supervised constantly	3.85 (0.404)
OT doors kept closed during operation	3.80 (0.403)
Number of persons in OT limited during operation	3.75 (0.501)
Defects in aseptic practice documented	3.71 (0.744)
Unscrubbed person not moving between two sterile fields	3.66 (0.594)
Circulating nurse staying in OT during operation*	3.26 (0.776)
Intraoperative conversation is aseptically important*	3.00 (0.901)
Disestablishment of Sterile Field α=0.617	
Gloves used during disestablishment of the sterile field	3.97 (0.173)
Bloody gloves not removed outside OT*	3.91 (0.290)
Not disestablishing sterile field during wound closure*	3.83 (0.414)
Scale mean	3.44
Scale α	0.782

*Items reverted into 4-point scoring so that higher numbers represent stronger recommendation agreement; α= Cronbach's α-reliability coefficient; OT= operating theatre

the intraoperative conversation as aseptically important received the lowest acceptance.

Also, the acceptance of two other recommendations, one for creating the sterile field less than one hour before operation, and another for the circulating nurse staying in the OT during operation were lesser than the others.

Several clinically-relevant recommendations did not reach acceptable internal consistency and were excluded. Table 21 introduces the excluded intraoperative AP recommendations for circulating nurses in the 2000, 2001 and 2013 measurements. Variation in the acceptance of recommendations existed.

Table 21 *The excluded aseptic practice recommendations for circulating nurses selecting items and establishing the sterile field.*

Recommendations for selecting sterile items and establishing the sterile field (n= in 2000/2001/2013)	2000 Mean (SD)	2001 Mean (SD)	2013 Mean (SD)
Sterile instrument table created inside OT (n=-/-/65) [b]	-	-	2.72 (1.166)
Sterile field not created near patient's head (n=89/84/ -)	2.63 (1.142)	2.69(1.075)	-
Most upper packages removed outside OT (n=98/93/67) [b]	2.58 (1.266)	2.95 (1.046)	2.78 (1.312)
Fluid container opened in previous operation not used (n=103/101/68)	3.38 (0.865)	3.38 (0.926)	2.68 (1.071)
Damaged sterile package not used* (n=103/100/-)	3.78 (0.463)	3.66 (0.655)	-
Double gloves used when exposing to infectious material (n=-/-/68) [a]	-	-	3.56 (0.835)
Fluid dispensed from a bottle only once (n=101/99/66)	2.48 (1.092)	2.55 (0.982)	3.79 (0.595)
Sterile item opened by unscrubbed person protected as long as possible (n=-/-/67) [b]	-	-	3.85 (0.557)
Sterile item not tossed onto sterile field* (n=104/104/66)	3.20 (0.900)	2.98 (0.975)	3.58 (0.681)
Sterile gloves not tossed onto sterile gown* (n=100/99/-)	3.03 (1.039)	3.03 (1.073)	-
Sharps and heavy objects presented onto a sterile field (n=101/96/66)	3.25 (1.108)	3.26 (1.069)	3.32 (1.025)
Sterile field of one m^2 is not big enough for any operation* (n=92/93/-)	3.39 (0.798)	3.32 (0.899	-
Surgical cotton textiles are not safe* (n=102/ 95/67)[b]	2.80 (0.975)	2.80 (0.941)	2.90 (0.956)
Splashes of poured fluid contaminate the sterile field (n=100/98)	2.32 (0.963)	2.55 (0.975)	-

* Items reverted into 4-point scoring so that higher numbers represent stronger recommendation agreement; OT= operating theatre; a) Appears in 2013 updated recommendation; b) evaluates local aseptic practices.

5.2.2 TOOS FOR SCRUB NURSES' ASEPTIC PRACTICES

The "Scrub Nurse Preparing to Work in the Sterile Field" scale (Table 22) measured self-reported AP recommendation adherence (Aholaakko & Metsälä 2018). The scale contained 13 statements, 5 of which focused on qualities of the selected sterile gown and 8 on the selection and use of the sterile surgical textiles. The eight surgical textile-related recommendations comprised a scale

with high internal consistency (α=0.87). Due to the better description of the pre-operative practices, we settled on a final scale with all 13 items, having an internal consistency of α=0.841. Deleting two recommendations would have improved the scale's internal consistency. However, the recommendations for not donning a sterile gown outside the OT and selecting role-related sterile gowns remained due to their importance in clinical practice.

Table 22 *Self-reported adherence of scrub nurse preparing to work in the sterile field*

Self-reported aseptic practices of scrub nurse preparing to work in the sterile field (n=68)	**Mean (SD)**
The sterile gown I use covers my back *	3.93 (0.401)
The sterile gown I use enables unrestricted movements *	3.64 (0.753)
When extending arms my sterile gown cuffs are covered*	3.79 (0.749)
I don't don sterile gown outside OT # *	3.87 (0.423)
I choose my gown related to my role in the sterile field *	3.94 (0.385)
I select surgical textiles considering patient-requirements *	3.42 (1.002)
I select surgical textiles considering the type of procedure *	3.75 (0.659)
I select surgical textiles considering anticipated blood loss *	3.40 (0.986)
I select surgical textiles considering duration of the operation *	2.85 (1.222)
I select surgical textiles considering volume of irrigation fluids *	3.22 (1.098)
I consider environmental issues in selecting surgical textiles *	2.49 (1.248)
I select surgical textiles complying the standards for them*	2.96 (1.224)
I select surgical textiles considering physical stress on them*	2.78 (1.253)
Scale mean	3.387
Cronbach's α-reliability coefficient of the scale	0.841

Items reverted into 4-point scoring so that higher numbers represent stronger self-reported adherence to the AP-recommendations; * Appears in 2013 updated AORN recommendations.

The self-reported adherence to recommendations for sterile gowning was high; all mean values were over 3.64 (maximum of 4 points). Additionally, the standard deviations for these recommendations were not as wide as those for selecting and using surgical textiles, indicating stability in responses to the sterile gowning statements. More variation was reported in adherence to recommendations for surgical textile use (mean values from 2.49 to 3.75). The lowest adherence was found in environmental standards. Three items were removed (using surgical mask, donning sterile gloves by using the closed technique, and using a sterile gown with proper sleeve size), which decreased the internal consistency of the scale.

Sixty-one recommendations were tested in order to construct a scale measuring the acceptance of AP recommendations according to the stages of operation: selecting items, and establishing, maintaining, and disestablishing the sterile field. No combinations with satisfactory α-values and clinically

relevant construction, according to the stages of operation, were found. The best clinical relevance and internal consistency (mean=3.48, α=0.824) was archieved by using 58 of the 61 items measuring the scrub nurses' work in the sterile field (Appendix 2).

The excluded recommendations focused on maintaining a 30 cm (≈1 foot) distance between unscrubbed person and the sterile field, conducting surgical hand preparation before every operation, and starting the disestablishment of the sterile field after wound closure. Removing eight recommendatons: sterile gown not worn outside OT; sterile gloves not worn over the main instrument table; both back and front side of sterile gown not sterile; gown sleeves considered sterile from 5 cm above the elbow to the cuff; neckline, shoulders and axillary regions of the sterile gown considered contaminated; items over sterile field covered with sterile barrier; draping distally from wound area; sterile field covered with a sterile drape during x-ray imaging, would strengthen the internal consistency of the scale. They remained due to their importance in measuring risks for sterility.

Closer inspection of the recommendations revealed variation in acceptance. The maintenance of sterility in gloving was measured with several items. The recommendation to select indicator gloves for risky operations was highly accepted (mean=3.95, SD=0.21) compared to recommending the closed-assisted gloving of surgical team members (mean=2.75, SD=1.08) and changing sterile gloves every 90 to 120 minutes (mean=2.46, SD=1.01). The acceptance of the recommendation to not establish a sterile instrument table outside the OT was low (mean=2.75, SD=1.18). It was left due to its importance for the internal consistency of the scale. The acceptance of the recommendation to change the entire set of instruments even if only one was found clamped closed was low (mean=2.75, SD=1.07).

A 58-item summation variable (n=68, mean 3.44, min=2.16, max=3.98) was used for testing differences in the acceptance of recommendations for scrub nurses working in the sterile field. No statistically significant differences were found using Mann-Whitney U-tests according to education, years of experience in OTs overall or at current OT unit, or according to work exposure to bloodborne infections.

The scrub nurses' self-reported adherence to recommendations for maintaining a sterile operating field was measured with 29 items. Three of the recommendations (not taking patient's bed into the OT, changing work attire daily, and not wearing artificial nails in the OT) had no response variance and, thus, were removed from the analysis. Additionally, due to their importance in continuously maintaining sterility, three recommendations (the sterile gown I use covers my back, the sterile gown I use enables unrestricted movement, and my arms extended sterile gloves cover cuffs of sterile gown) were retained.

Table 23 *Self-reported adherence to aseptic practice recommendations for maintaining the sterile field among operating theatre nurses.*

Self-reported adherence to aseptic practice recommendations during maintenance of the sterile field**	Mean (SD)
I change soiled surgical attire during work day *	3.75 (0.560)
The sterile gown I use covers my back *	3.92 (0.407)
I change wet surgical mask during operation *	2.29 (1.155)
I don't eat or drink during operation in OT #	3.63 (0.517)
I use protective eyewear in the sterile field *	3.20 (1.003)
I don't cover injection needle by my hands # *	2.85 (1.064)
I don't extend knife directly to the receiver #	2.35 (1.110)
I handle needles in needle-holder with instrument	2.71 (1.155)
During operation I discuss operation-related issues only*	2.40 (0.787)
I avoid touching patient's ski during operation	2.69 (0.999)
I handle instrument minimally during operation	3.09 (0.947)
I use suction tube in removing surgical smoke	2.40 (0.949)
I avoid handling sterile drapes *	3.31 (0.865)
I cover the wound before cleaning the patient's skin	2.35 (1.192)
I replace surgical mask after coughing *	1.94 (0.966)
I don't put sharps straight onto the sterile drape # *	3.42 (0.998)
I avoid handling instruments used in the operating field	2.63 (1.112)
My head covering completely covers my hair in OT *	3.60 (0.607)
The sleeves of my sterile gown are not too excessive *	3.06 (1.236)
I wear shoes worn only in OT*	3.63 (0.876)
I remove piercings before my sift starts in OT *	2.18 (1.402)
I don't work in OT with dermatitis in my hands # *	3.55 (0.811)
I don't use fingernail polish when working in OT *	3.75 (0.501)
The sterile gown I use enables unrestricted movement *	3.65 (0.759)
My arms extended gloves cover cuffs of sterile gown*	3.78 (0.760)
I remove necklace before practicing in the sterile field*	1.89 (1.301)
Scale mean	3.00
Cronbach's α-reliability coefficient of the 26 items scale	0.735

Items reverted into 4-point scoring so that higher numbers represent stronger agreement to the recommendations; * Appears in 2013 updated AORN recommendations; ** n=65

The internal consistency of the 26-item scale (Table 23) was acceptable (α=0.735). The mean values of the items varied from 1.89 to 3.92. The high standard deviation values of the recommendations with low mean values indicate wide variation in the recommendation adherence.

Closer inspection of the results found OT nurses reporting high and stable adherence (mean values > 3.5; SD values from 0.41 to 0.87) to 9 of the 26 recommendations focusing on maintaining the barrier effect of the surgical gowns, caps and gloves, controlling for vector-borne contamination via skin or

dust particles, and avoiding eating and drinking during an operation. The recommendations for controlling sharps in the sterile field were not all well adhered to. Low adherence was reported to the recommendation to not extend a surgical knife directly to the receiver (mean=2.35, SD=1.11). The highest adherence was found to the recommendation to not put sharps straight onto the sterile drape (mean=3.42, SD=0.99). Adherence to wearing protective eyewear was found to be high, but not very consistent (mean=3.20, SD=1.00). The lowest adherences were reported to the recommendations controlling airborne contamination by replacing the surgical mask after coughing (mean=1.94, SD=0.97) and removing necklaces when working in the sterile field (mean=1.89, SD=1.30).

A 26-item summation variable (n=69, mean=3.02, min=2.12, max=4.00) was constructed to measure differences in the self-reported adherence to AP recommendations using Mann-Whitney U-tests. No statistically significant differences were found.

5.3 ASEPTIC PRACTICE-RELATED STRESS (I)

In 2003, a qualitative study (I) was performed investigating the realisation of the local AP recommendations in the study hospital OT. The researcher (T.-K. A.) videotaped altogether 31 breast operations and evaluated the realisation of the intraoperative AP from the recordings according to the tool (Aholaakko & Metsälä 2018).

Of the 31 breast operations, 17 lumpectomies and 14 mastectomies were observed. Patients of the observed 31 operations were between 41 and 94 years old. Of the patients, 11 had a reoperation after this operation. The time of operation from incision of the patient's skin to wound closure varied from 15 to 130 minutes, according to the video-assisted observations. In the study OTs, the number of personnel varied from 4 to 11 during establishment of the sterile field, typically (mode) six persons. The number of scrubbed surgical team members working in the sterile field varied from two to four, typically two persons. The number of people present in the OT during operation varied between five and ten, typically five persons. The number of OT doors opened varied between 0 and 19. The average number of door openings was seven, typically six. During 25 operations, no pause for diagnostic reasons was needed. In 6 operations, the diagnosis was completed from 1 to 24 minutes after the specimen and samples. In five operations, the intraoperative conversation was not related to the operation.

Seven of the 31 observed operations led to post-operative SSI. Five were mastectomies and six axillar evacuations. The amount of bleeding during operations with SSIs varied between 100 and 400 ml. Contamination of the sterile field or item was observed in 10 of 31 operations. After three contaminated operations, there was a post-operative SSI. After one operation, the sterile gown was found to have been penetrated with blood, no post-

operative SSI was reported. During two operations, the sterile gloves were found perforated. After one of these two operations, an SSI was reported. A post-operative SSI was reported after six of the seven operations after which the sterile drapes were found to have been penetrated with blood. In seven operations, the health status of the personnel was compromised. Among these seven operations, one post-operative SSI was reported.

The viewpoint of the circulating nurse was selected due to the best possible visibility of the APs. In the end of the stimulated recall interview, the author gave feedback regarding the actual AP for the interviewed OT nurses. The nurses reflected on the situation in a very open manner. This enabled the collection of rich material for qualitative analysis about the clinical performance of intraoperative APs.

The realisation of the recommended intraoperative AP caused stress. Time, power, patients, equipment, experiences and morals were AP-related stressors present in the operation. The circulating OT nurses reported using situation- and person-specific means to reduce their AP-related stress. The used means varied according to the nurses' experience. The AP-related stress was reduced by generic means: safe; peaceful; competent and relative nursing practices. Safe practice included exact, anticipative and ensuring performance of APs during the operation. Competent practice was comprised of responsible, patient-centred, collegial and skilled means of stress reduction. Peaceful practice was defined as facilitating and silent working modes. Relative practice included person- and situation-specified means to reduce the AP-related stress, and both passive and active withdrawal from performance of recommended APs.

5.4 RISK FACTORS FOR SURGICAL SITE INFECTIONS IN BREAST OPERATIONS (II)

Before and after the co-creation of the intraoperative AP recommendations in the study hospital OT, the SSI rates were calculated in both study and comparison hospitals among 982 clean and clean contaminated breast operations (II). Lumpectomies (n=700) and mastectomies (n=282) studied. No statistically significant improvement or differences between the study and comparison hospitals existed in SSI rates after the AP co-creation. The data collected before and after AP recommendations documentation, was combined to measuring SSI risks in breast operations. The mean operation time was 64.83 minutes. The 75th percentile cut time was 87 minutes. Sixty-six (6.7%) SSIs were identified (Table 24). Most of the SSIs were deep incisional (56.1%), followed by superficial (33.3%) and breast-space infections (10.6%). In the study hospital, the overall rate of post-operative SSI was 8.0%. In 2000, the rate was 7.7% and in 2001 8.3%. In the comparison hospital, the overall SSI rate was 5.8%. In 2000, the SSI rate was 4.0% and in 2001 it was 7%. The

differences between or within hospitals before and after the AP recommendation co-creation were found to not be statistically significant.

Table 24 Infections in breast surgery (n=982) in 2000 and 2001.

	Types of surgical site infections (n=66)				**Other infections in breast operations**			**Ope-rations**
Time	Superfi-cial SSI n= (%)	Deep SSI n= (%)	Brest space SSI n= (%)	All SSIs n= (%)	Bacter-emia n= (%)	Non-SSI absces-sus +1 month post OP n= (%)	Unspecific infection n= (%)	
In 2000*								
Study hospital	4 (26.7)	10 (66.7)	1 (6.6)	15 (62.5)	0	0	2 (0.9)	196
Compa-rison hospital	2 (22.2)	6 (66.7)	1 (11.1)	9 (37.5)	1 (0.4)	0	0	225
Total 2000	6 (25)	16 (66.7)	2 (8.3)	24 (100)	1 (0.2)	0	2 (0.5)	421
In 2001*								
Study hospital	5 (27.8)	9 (50)	4 (22.2)	18 (42.9)	1 (0.5)	1 (0.5)	2 (0.9)	217
Compa-rison hospital	11 (45.8)	12 (50)	1 (4.2)	24 (57.1)	0	0	0	344
Total 2001	16 (38.1)	21 (50)	5 (11.9)	42 (7.5)	1 (0.2)	1 (0.2)	2 (0.4)	561
Overall 2000 & 2001	22 (33.3)	37 (56.1)	7 (10.6)	66 (6.7)	2 (0.2)	1 (0.1)	4 (0.4)	982

*differences between hospitals were not statistically significant

In addition to SSI, other infections were also identified in the patient records. In the study hospital, one bacteremia was identified before and one non-SSI abscessus after co-creation of the AP recommendations. In the comparison hospital, one bacteremia was identified before co-creation of the AP recommendations. In the study hospital, two non-specified infections were identified both before and after the AP recommendation co-creation.

Both patient- and procedure-related SSI risk factors were identified. Increased SSI risk was found among patients with an ASA score of 3-5 compared with patients having ASA scores of 1-2. Higher risk was identified in operations with contaminated or dirty wound classes than in clean or clean-contaminated operations. A BMI $\geq$25 kg/m^2 and re-operation increased the SSI risk.

The multivariate logistic regression models predicted the SSI risks among all breast operations. Four patient-related risks were found to be statistically significant: an ASA score of 3–5; contaminated or dirty wounds; BMI more than 25 kg/m^2 and re-operation. Re-operation also predicted increased SSI risk among both in lumpectomy and mastectomy patients. A high BMI increased the SSI risk in lumpectomies. Use of a surgical drain predicted increased SSI risk in all operations, being statistically significant in lumpectomies but not in mastectomies.

6 DISCUSSION

The connections between APs and outcomes of the surgical interventions studied and reported by Lister (1870a&b) and Brewer (1915) at the end of 19th century were well-known. The early AP guidelines were the outcomes of their local development works and they were implemented as the discipline-specific orders of responsible surgeons' long time. The legacy of Lister and Brewer is still silently visible in contemporary OTs. For many decades, the professional authority of surgeons enabled unquestionable obedience, making the surgical team members follow the present clinical APs. The more the surgical techniques developed, the wider the accountability of the nursing discipline became concerning intraoperative APs. Currently, the OT nurses possess the main responsibility for the intraoperative AP in Finnish OTs.

In the study hospital, the lack of mutually constructed, tested and accepted AP recommendations were found to make the intraoperative AP varied, individual (I & III) and stress-inducing (I) within the surgical teams. Limited or lacking documentation of the intraoperative AP-related data also barred the clinical outcome evaluation (II) of the costly intraoperative APs. A lack of concensus existed about the clinical practices, and also about the discipline-specific roles in interdisciplinary surgical teams (I). Expert OT nurses recognised the situation and participated in the development work with passion.

The total response rates for all three surveys investigating the acceptance of and adherence to intraoperative AP recommendations remained low (III). This barred the data analysis and publication of the results. To some degree, the development work of the intraoperative APs suffered from withdrawal of some OT nurses and physicians. This may be due to the uncertainty about the accurate APs or their own knowledge and skills. The video recordings revealed the surgeons' deep concentration while operating to limit their capacity to focus on the APs. On some occasions, the hurrying and pressing reactions of the surgical team members were visible when the circulating nurses performed recommended APs. The local validation of the international guidelines and recommendations met with some resistance in the form of commenting on the survey and withdrawing from the development work. During the stimulated recall interviews (I), the OT nurses considered the evidence-base of APs to be vague and the reasoning of present clinical APs challenging. The survey results also supported this interpretation. A higher education background turned out to be one of the factors for lower acceptance and self-reported adherence to APs (III).

The endpoint for the development came in the form of institutional and organisational changes both in hospitals and in higher education institutes. Within the nursing higher education, the continuous development of evidence-based technical norms for intraoperative APs did not manage to

become one of the core competences to be developed within the nursing discipline. Despite the clinical needs, academic (Academy of Finland 2003) and philosophical support (Niiniluoto 1993; 1996; 2003) for the development of clinical nursing, in this case the APs as evidence-based nursing-specific competencies, the long effort to develop intraoperative APs ended. Continuous organisational changes and lack of funding compromised the continuity of the cooperative project between the University of Applied Sciences and university hospital.

6.1 DEVELOPMENTAL EVALUATION OF INTRAOPERATIVE ASEPTIC PRACTICES

In this developmental evaluation process of intraoperative APs, it was considered essential to justify the value of the AP recommendations for the evidence-based practice and patient safety in the complex OT environment (Patton 2011). According to Shortell and Richardson (1978), in healthcare evaluation the emphasis is on the importance of the scientific method in attempting to isolate the causes of particular events or outcomes. The primary distinction between programme evaluation and basic or non-evaluative research lies not in the methods but rather in the use of the knowledge acquired. They advise to meet these demands by seeking answers to the following questions: 1) *why* the results were less than expected, 2) *wha*t can be done to improve the programme, and 3) *how* should such changes take place.

6.1.1 WHY THE RESULTS WERE LESS THAN EXPECTED

In the study hospital, and also nationally, some of the reasons *why* the intraoperative APs were not performed as comprehensively as described may be due to the too universal and unstructured AP recommendations which also lack evidence-based contents. The national instructions for intraoperative AP do not cover clinical practice. The heterogeneity of the instructions was visible in several survey measurements as wide standard deviation (SD) values and missing values caused by lack of study participants. The AORN (1991 & 1999) recommendations were used as an evidence baseline for the evaluative development. They did not meet the demands for evidence-based APs, in either Finnish or the OTs of the study hospitals. The development of some of the materials, such as the barrier materials (drapes), used in the observed operations challenged the implementation of the AORN-recommended practices. The drapes used were disposable, and nurses considered them to be resistant to strike-through contamination (Mangram et al. 1999; Blom et al. 2000; Blom et al. 2002a & b; Alexander et al. 2011; Falk-Brynhildsen et al. 2012; Overcash 2012) of the sterile field. Perhaps they trusted them too much under certain conditions. The partly out-of-date recommendations did not

always meet the real clinical situations and nurses had no evidence strong enough for reasoning their assumptions in making clinical desicions.

During the literature reviews for updating the follow-up survey (III), the lack of clinical coverage and conceptual diffusion in recommendations and guidelines for intraoperative APs was found. The lack is still present today. The CDC 2016 guidelines (Berríos-Torres et al. 2017) and the updated WHO recommendations (Storr et al. 2017) both lack a systematic definition of intraoperative APs. They both focused mainly on the core components of effective IP and IC programmes. In the WHO recommendations, the evidence-based guidelines for hand hygiene was introduced as the only clinical procedure. In the programme implementation, the WHO working group pointed out the adaptation of the guidelines into the local context. They also advised taking into account the available resources, culture and public health needs as well as the feasibility and costs in low resource settings. The WHO work group required sound implementation strategies and practical tools in facilitating programme adoption without introducing any for clinical use.

Some of the intraoperative AP measures, for example disinfection of the surgical site, have alternative procedures with an ongoing search for evidence and cost-effectiveness (Parienti et al. 2002; Al-Naami et al. 2009; Magalini et al. 2013). The continuous follow-up of tested evidence is one of the cornerstones for sustainable intraoperative APs. In some other international cases, the quality and quantity of evidence used in the reasoning of AP recommendations and guidelines turned out to be biased and unsatisfactory. When familiarising oneself to the arguments of international guidelines and recommendations, it is beneficial to reflect on their value and evidence-base. In some cases, the reason for critiques against the existing recommendations was purely financial. Some of the recommendations were also based on insufficient evidence with only one reference. Woodhead et al. (2002) for example found no evidence that perforated surgical gloves increased the incidence of SSI. They recommended that perforated gloves do not indicate a glove change. They also recommend that it is not neccessary to remove wedding rings for operation and no hair cover is needed in the OT outside the sterile field during operations other than orthopaedic prostheses.

Withdraval from the use of laminar airflow over the sterile surgical field was recommended and challenged by comparing its cost-effectiveness with other measures, like antibiotic prophylaxis and antibiotic impregnated cement in hip arthroplasty (Smyth et al. 2005; Brandt et al. 2008; Merrollini et al. 2013). The conclusions of a recent meta-analysis (Bischoff et al. 2017) assessing the relationship between SSIs and laminar airflow recommend not using the expensive measure in orthopaedic operations. Jutte et al. (2017) found weaknesses in the study and suggested continuing the using of laminar flow in selected orthopaedic operations. From the AP viewpoint, the OT doors are important to keep closed, the use of powered instruments controlled, and the positions of instrument tables and members of personnel in the sterile field documented and controlled, so that they do not disturb and contaminate the

air in the wound area. According to the argumentation above, more detailed procedure-specific AP guidelines are required.

The existing situation of resistant microbes calls for reflection regarding the withdrawal from existing AP guidelines and recommendations with care. Fraser et al. (2015) found no benefit by using expensive setups in the prevention of staff-sourced contamination in orthopaedic operations. These recommendations do not completely respect the three zone OT model of Friberg & Friberg (2005), recommending to avoid bacterial dispersion into the sterile operational field by allowing only the necessary surgical team members and equipment inside the ultraclean area. Other members of personnel are recommended to stay outside it. Also, the clean zone is recommended to be designated for the opening of sterile equipment, gowning and gloving. Equipment such as diathermy, suction, or a heart–lung perfusion machine are recommended to be placed in the clean zone. Unsterile surgical attire is recommended to be used in the semi-clean zone outside the laminar airflow.

The current situation with varying and lacking evidence for intraoperative AP is challenging. Both education and research are required. In the 1990s and early 2000s, the substance of Finnish nursing education and research focused on the experiences of the patient and in theory-building, instead of creating and testing technical norms for nursing practice (Vehviläinen 1998; Academy of Finland 2003). These conditions are still influencing the content-related choices and developmental attitudes in nursing higher education. In the future, it is crucial to join in the international research and educational networks and bodies, of which the ARIBO Project (Birgand et al. 2014), facilitating the evidence-based development of intraoperative APs as cornerstones of cost-effective and safe surgical care, is a good example.

The contemporary AP recommendations used in Finnish perioperative nursing education are following both evidence and tradition. The Finnish intraoperative AP recommendations are not nationally standardised and are not focused deeply enough on clinical intraoperative practice. The learning of intraoperative APs, if existing at all in nursing curricula, takes place during a few theoretical and "laboratory lessons" and practical placements for some of the students. In advanced institutes, the intraoperative AP knowledge and skills are achieved during simulation studies.

In addition to nursing students, the clinical OT nurses also educate the medical students in surgical environments. That is why it is important to strengthen the evidence-base of the knowledge and skills and raise safety-supporting attitudes among the future clinical professionals. Nationally, the financial cuts risk the development of evidence-based clinical education and development of intraoperative APs. The temptation to replace all the institutional lessons by apprenticeship learning in OTs is excessive.

Professional OT nurses in the study hospital defined the need for interdisciplinary improvement work and accepted the participation of the external evaluator in developing the clinical APs in the study hospital OTs. This practice might be beneficial in performing the future evidence-based

continuous clinical developmental evaluation of APs by assembling the limited resources of hospital and higher education personnel.

The results of these observational studies exposed the variation in attitudes, knowledge, skills and adherence to intraoperative APs (I-III), supporting the need for evidence-based higher education of intraoperative APs. These studies may serve as a baseline and provide tools for developing the Finnish interdisciplinary IC and IP education together with clinical experts.

6.1.2 WHAT WAS DONE TO IMPROVE INTRAOPERATIVE ASEPTIC PRACTICES

The effort regarding *what was done* during this evaluative programme to meet the demands of developing the existing APs started by the formulation of the recommended APs for OTs of the study hospital. The advice of Robson (1995: 154-155) were followed as carefully as possible in planning this evaluative research. Robson stated that the presence of all the neccessary theoretical knowledge is not necessarily required in the early phase of research. This made it crucial to create a model about all the important factors the researcher assumed to be in connection with the focus and context of the research. Like Robson indicated, the initial AP model (Figure 2, P. 53) progressed during the research. Because it was not possible to study all the factors, it was considered important to carefully report the choices made during the research process. The selection criteria for research participants and the description of the data collection phases, incidences, practices and processes were considered important. The initial aim defined by the OT nurses was to minimise the alterations in APs by documentation of explicit AP recommendations.

The pre- and post-documentation data collection was performed concerning the knowledge, attitudes and opinions of APs among the personnel of both study and comparison hospitals. To facilitate the follow-up of the recommendations for intraoperative APs, the researcher participated in the processes of formulating a digital perioperative documentation tool together with OT nurses and an expert in information technology in the study hospital (Liljeblad et al. 2002) with the methodological assistance of Newman and Brown (1996) and Patton (1990). This document served in the data collection of the SSI study (II).

The post-documentation data collection by hardware survey instruments took place in both study and comparison hospitals in 2001. A follow-up on-line survey was performed in 2013 (III). The clinical AP performance and IC documentation of breast-operated patients (II) were assessed to explore factors connected to SSI after breast operations. The evaluation of APs in breast surgery performed by video-recorded stimulated recall interviews revealed challenges in decision making that caused stress in intraoperative AP. The nurses in the study hospital found the interviews useful and valued the structured feedback they obtained about their intraopertive AP at the end of

the stimulated recall interviews. All these individual studies enabled the development and testing of model for intraoperative aseptic practices for future co-creation.

6.1.3 HOW THE DEVELOPMENT OF INTRAOPERATIVE ASEPTIC PRACTICES COMPLETED

How the chosen development of the intraoperative APs was completed emphasised the participation of the entire OT personnel and the use of evidence-based literature in reasoning the decisions during the study programme. The development work started by implementing the heavy qualitative naturalistic-formative approach of evaluative research aiming to develop, create new or change old programmes using both qualitative and quantitative methods of data collection and analysis (Patton 1990). During this evaluative programme, the cooperation with the researcher and OT personnel were found to be essential. Without the clinical experience of the OT personnel and the evaluator, the recommendations would not have been clinically relevant in the actual contexts and situations, the economical demands or the acceptance of the OT personnel. The chosen approach turned out challenging to apply due to limited resources of the evaluator. Some financial support was obtained in the early phase of the programme. Perioperative nurses' associations in Finland, Europe and globally trusted the importance of the development work and supported the professional discussions around the topic. Without this support, the programme would never have been completed.

Due to to the long period of reporting the research results, it is considered useful to review the methodological approaches used in this study project. This report was constructed by amalgamating the methods used in traditional healthcare evaluation (Campbell & Stanley 1963; Shortell & Richardson 1978; Williamson 1978), real-life research (Patton 1990; Robson 1995), developmental evaluation (Patton 2011) and the present assessment culture approach used in current competence-based and performance assessment in education (Baartman et al. 2007). This whole process created a well-developed individual interest in evaluative development of intraoperative APs (Hidi & Renninger 2006).

In this process, the intraoperative AP assessment was not only used in a summative way, but also in guiding the OT personnel, particularly nurses, in performing the intraoperataive AP. Both the outcome and process feedback were provided regarding their AP performance during the process. So the delay and difficulties in publishing the local and partly negative results perhaps did not harm the clinical AP development in the study hospital.

A mix of methods were used to reach the multiple dimensions of the intraoperative AP (Baartman et al. 2007). An epidemiological approach was used in the SSI risk assessment (II). A qualitative approach opened the organisational challenges in AP (I) and the classical test theory was used in

selection of the assessment criteria constructing the tools for intraoperative AP (III). Due to the small research groups, the α-values for scale reliabilities were high, but the tools did not manage to cover the overall focus of the evaluation, the whole of the intraoperative AP.

The semi-structured observational AP assessment and the stimulated recall interviews assisted by the video recordings enriched the understanding about the barriers and facilitators of clinical practice (I). It also supported the conclusion that it was not beneficial or ethically right to assess the competences of the study participants. The external factors barred the criterion-referenced APs and the competence-based assessment would not be fair. Baartman et al. (2007) summarised the assessment culture rejecting the fundamental belief that there can be universality of meaning as to what any grade or score represents and that it is possible to separate the goals of education from the means for their completion.

The ideas introduced above were applied in the assessment of clinical AP guideline adherence. The philosophy of technical norms (von Wright 1963; Niiniluoto 1993, 1996, 2003) supported this approach. The intraoperative AP recommendations were considered as results of the evaluative development constituting knowledge about intraoperative AP. The local AP recommendations were constructed as outcomes of mutual definition through the actions, skills and concepts of the participating OT personnel. They are real-life statements concerning the relationships between means (AP) and ends (SSI / adherence to AP recommendations), even the testing of them was difficult. They were constructed to provide goals for intraoperative AP as action, expressing actual professional expertise and facilitating the efficiency of surgical practice.

6.2 LESSONS LEARNED FOR FUTURE DEVELOPMENT OF INTRAOPERATIVE ASEPTIC PRACTICES

The observed intraoperative APs consisted of complex but not open-ended tasks. The assumption that the lack of properly performed APs will directly cause an SSI gained no direct support from the results of this developmental evaluative project. The importance of some individual AP measures used in contemporary intraoperative APs may be over-estimated and not having direct evidence-base. Nevertheless, the contemporary APs are considered clinically important and used as means to prevent SSIs by reducing the routes of contamination and improving surgical safety (AORN 1991 - 2013; Hallmo & Naess 1991; Wright & McGree 1993; Stafford et al. 1995; EU Council 2009; Allegranzi et al. 2011; Onwubiko et al. 2014; Jutte et al. 2017).

The reported scales did not manage to cover all the AP measures the circulating nurse or the scrubbed team members perform during the operation to establish, maintain and disestablish the sterile operation field.

Consequently, it was found a fundamental necessity to further develop the existing AP recommendations as evidence-based guidelines for multi-professional performance in preventing SSIs (Saint et al. 2013) and further study the challenges and requirements for improving surgical occupational and patient safety (Flaherty & Wick 1993; Telford & Quebbeman 1993; Mangram et al. 1999; EU Council 2009; Flin et al. 2006; EU Council 2010; Alexander et al. 2011). More research in larger study groups are important to complete.

The results of the international literature review completed during the follow-up indicated that by focusing AP guidelines on practical improvements and risk-related strategies using advanced structured implementation protocols, it is possible to improve guideline adherence (Alerany et al. 2005; Schelenz et al. 2005; Burkitt et al. 2009; de Korne et al. 2012; Cutter & Jordan 2004). The importance of identifying the professional characteristics that create barriers to AP recommendation adherence, such as work experience, perceptions of invulnerability, and a tendency to be dismissive of occupational injuries (Cutter & Jordan 2004 & 2012) supports the findings of both the qualitative study (I) and the measured occupational exposure rates in the study and comparison hospitals. These characteristics are worth focusing on. The hazards in safety practices in handling sharp objects during operations and the documentation of occupational exposure to bloodborne infections are well-reasoned critical incidents for continous clinical AP evaluation.

Internationally, punishing means are also used in improving the adherence to intraoperative APs. Osborne (2003) reported the highest compliance rates with double gloving in an Australian state where compliance to mandated IP guidelines for health professionals was linked to certified nursing registration. This kind of "facilitation" of AP adherence may be discussed when the guideline adherence is totally lacking or varies a lot among OT personnel (Jeong et al. 2008) or by surgical specialty (Borgey et al. 2012). Instead of using authoritarian OT discipline to compel guideline adherence (Madhaven et al. 1999), it may be preferable to implement the means reported during the stimulated recall interviews of circulating nurses (I). Performing the evidence-based AP protocols in a calm and competent manner, taking into consideration both the patient safety and the integrity of the surgical team members were reported means. The results of the qualitative study pointed out the need of future research to increase the understanding of the Finnish OT culture. Sinkowitz-Cochran et al. (2012) and Saint et al. (2013) reported the role of the OT culture as important in implementing effective IP programmes, such as immediate personalised feedback (Luke & Alavosius 2011; Son et al. 2011), improvement of traditional AP performance, and beneficial in the use of technical applications securing guideline adherence (Lee et al. 2013). Novel developed measures, for example the motion-tracking system (Birgand et al. 2014), facilitate and enable real-time data collection, enabling the use of feedback based on statistical methods implemented in intraoperative AP observations.

Patient-related characteristics caused stress in performing AP. They also decreased the AP adherence (I) in the study hospital OTs. Results of international studies support this finding. Female gender of the patient (Vaisbrud et al. 1999) or the patient having a low risk of SSI (Vaisbrud et al. 1999; Cutter & Jordan 2004) barred AP recommendation adherence. Perceptions concerning the patient's lifestyle, sexual orientation, nationality, or infection status were reported as improving guideline adherence (Cutter & Jordan 2004 & 2012). This kind of selectivity in clinical practices is important to understand and remedy to be able to expand AP adherence equally for all patients.

Environmental characteristics were reported mainly as barriers to AP adherence. Having limited time for completing the operation was found to reduce the adherence to AP recommendations in the stimulated recall interviews (I). The results of Cutter and Jordan (2004 & 2012) support these findings. Vaisbrud et al. (1999) reported reduced AP adherence during unfamiliar operations. This indicates the importance of creating strategies for stable AP implementation in varying situations and facilitation of the professional performance of intraoperative AP.

Circulating nurses in the study OT reported (I) their AP adherence as depending on the quality of equipment and protocols. The results of Burkitt et al. (2009), Cutter and Jordan (2004, 2012) and Welc et al. (2013) support these findings. Differences in structural factors, like the availability of equipment and staffing levels, were reported as correlating with healthcare outcomes in the study of Lilford et al. (2004).

Personal discomfort of personnel due to IP measures reduced AP adherence in the studies of Parienti et al. (2002), Osborne (2003), Cutter and Jordan (2004 & 2012) and Welc et al. (2013). OT personnel reported avoiding the use of uncomfortable personal protective equipment and implementation of unclear protocols. In international studies, comfortable equipment and actual risk for both occupational infections and SSIs improved AP adherence (Vaisbrud et al. 1999; Parienti et al. 2002; Cutter & Jordan 2004; Al-Naami et al. 2009). The interview results gained support from these findings. This highlights the need to develop supplies and equipment that are comfortable for clinical staff to use.

In the beginning of this developmental evaluation work, no systematically developed evidence-based AP guidelines existed for the holistic performance of intraoperative AP in the sterile operation field. According to international research findings, a lack of clarity (Cutter & Jordan 2012) and standardisation in orders (Burkitt et al. 2009), as well as a lack of concise and deliverable policies (Cutter & Jordan 2012), are obstacles for AP guideline adherence. These limitations related to the lack of proper intraoperative AP documentation exhibited the assessment and reporting of both the performance and impact of intraoperative AP in defining the SSI risk factors in breast surgery (II).

Evidence-based perioperative nursing documentation was developed in Finland during recent decades (Junttila et al. 2005 & 2010). In testing and implementing international nursing diagnoses into the Finnish perioperative settings, it was found that they are inaccurate and limited in describing perioperative patient care in Finnish hospitals (Junttila et al. 2005). Only one of the most often used diagnoses, risk for infections, focused on AP. In further development exploring the core elements of perioperative care, Delphi panellists suggested 'creating the sterile field', 'maintaining the sterile field, instrumentation' and 'breaking down the sterile field and postoperative observation of the operation area' as essential in perioperative care (Rauta et al. 2012). Of these suggestions, all but 'maintaining the sterile field, instrumentation' were found to be descriptors of perioperative care when testing them in Finnish perioperative settings (Rauta et al. 2017).

6.3 FUTURE DEVELOPMENT OF EVIDENCE-BASED INTRAOPERATIVE ASEPTIC PRACTICES

This current study is a minor local response to the global infection prevention and control call aiming to draft tools for the development of evidence-based intraoperative AP. In this study, the concept of AP was introduced, analysed and developed as a main concept of an initial model for IP and IC interventions preventing the surgical wound area of perioperative patients from contamination, the surgical personnel from occupational exposure to infections in the multiprofessional context of perioperative care and the OT environment from contamination. The construction of the model was found to be necessary and beneficial in developing and evaluating the intraoperative APs in one Finnish University Hospital during the years 1996-2003. In the future, it may also serve as a basic concept in facilitating the development of the evidence-based intraoperative AP guidelines as a situation-specific theory for AP in the OTs (Im & Meleis 1999).

According to Lilford et al. (2004), interpreting healthcare evaluation outcome data by using common variables like mortality and morbidity rates may be over-interpreted. Good evaluation criteria are evidence-based, agreed upon and include action. The safety and quality measurements in healthcare are essential in assessing diseases and therapeutic processes (Scobie et al. 2006). In addition to common variables like mortality, the need for selecting indicators in benchmarking the health system and improving and reporting on its performance are defined. Indicators may not be used as absolute measures of quality or safety, but as identifiers of areas for deeper regional or local analysis. Measurement on clinical processes may serve as a practical instrument to stimulate change. Defining local problems, understanding when a change is a real outcome of improvement measures, as well as timely and repeatable quality assessment measurements are all challenging to undertake.

Evaluation of intraoperative AP as a clinical process indicator reflecting when quality of care meets the demands introduced above. After the critical selection of evidence-based criteria according to the logical AP model, intraoperative AP is possible to measure. Before AP measurements can be implemented into the clinical care, the AP standards are crucial to document and test in interprofessional contexts. After that, the evaluation of AP guidelines can be performed as part of daily clinical work. Care documents in which intraoperative APs are documented according to agreed upon, evidence-based and, when necessary, procedure-specific criteria are easily reachable for evaluative and research purposes.

According to Duckett et al. (2007), public services, like hospitals, regularly collect and analyse data for national and/or regional administrative purposes. This routine data includes information on the demographic characteristics of the patients, the principal diagnosis, other conditions treated, and procedures performed. The regular healthcare evaluation coding standards (e.g., WHO 2017; CDC 2016a) provide the methodological determinants for data collection and analysis. Clinicians are, at the core, consultants in the creation of regularly monitored clinical indicators of care outcomes.

Lack of relevant, openly available clinical criteria for AP documentation is an important issue requiring immediate improvement. The classifications and descriptors for perioperative care introduced by Junttila et al. (2005 & 2010) and Rauta et al. (2012 & 2017) are, at a very general level, for serving in the assessment of clinical practices like APs. Instead, they may serve as higher level structures for intraoperative APs. It is possible to test and develop the initial model for intraoperative AP (page 57) as part of these structures. By this process, a more comprehensive but specific classification for testing the clinically relevant evaluation criteria for intraoperative AP may be reached. A well-tested and accepted model for intraoperative APs also enables focusing on procedure-specific recommendations in the future.

Scobie et al. (2006) pointed out that gathering data on measures of the safety and quality of systems that are structural, valid, reliable, accurate, timely to collect, meaningful, relevant and important requires resources and structural investments. In improving intraoperative AP in an interdisciplinary and interinstitutional manner, co-creation is needed. The results and tools describing the intraoperative APs developed in this study may serve as a baseline in future co-creation. They construct a structure for AP-related technical norms being factual statements concerning relationships between means and ends in intraoperative IC and IP. As evidence-based guidelines, they will provide goals for practical intraoperative action by expressing professional expertise and facilitating the efficiency of practice (von Wright 1963; Niiniluoto 1993, 1996, 2003).

Niiniluoto (2003) presented that technical norms are useful for practical purposes only upon further conditions: 1) they should have certain social relevance in real situations and 2) they should be at least potentially acceptable for some social group. Technical norms contain evaluative and normative

terms and are value-based varying from a positivistic ideal of value-neutral science. As conditional statements, technical norms do not require a commitment to the value premises. Technical norms are binding only for those who accept their conditional value premises. In the past, AP recommendations were not always deduced from general theory but were typically supported "from below". Time being the demand for an evidence-base for professional skills and actions facilitated the development of AP recommendations. First they were cookbook-like orders reasoned by everyday experience, currently they are developing as evidence-based causal regularities and finally they will be technical norms.

According to Niiniluoto (1993, 1996& 2003), action, skills and the concepts of the profession contribute to the scientification of human practice, so that the results of it should be rules of action which at the same time constitute knowledge. These ideas also gain support from Rowley et al. (2010), who pointed out the importance of a theory and practice framework in the implementation of aseptic non-touch-technique. Combining evidence and clinical practices may serve as a trigger in developing the first situational and in time being better developed individual interest (Hidi & Renninger 2006) of OT personnel in performing and developing safe intraoperative APs.

Hidi and Renninger (2006) identified that the well-developed individual interest is characterised by positive feelings, more stored knowledge and more stored value for particular content than for other activities, including emerging individual interest. Intentional and evidence-based development of interest in APs according to psyco-educational (Hidi & Renninger 2006) or social cognitive (Rosenstock 1974; Seto et al. 1991; Gershon et al. 1999; Seto 1995; Nesler et al. 1999; Odgen 2003; Michie et al. 2005; Efstathiou et al. 2011) models may facilitate the professional interdisciplinary performance of intraoperative AP. In avoiding AP-related stress (I), shared professional respect, shared contents and procedures, as well as shared development projects, are valuable in facilitating the interest engagement in the assistance of both affective and cognitive factors guiding the intraoperative AP of interdisciplinary teams.

6.4 RELIABILITY AND VALIDITY OF THE STUDY

Both qualitative and quantitative methods were used in this study, combining the elements of testing culture and assessment culture in the evaluation. Due to the local nature of the processes and outcomes, numerous limitations existed in this study. In the early phase of the study, the methods for searching and creating evidence were coarse. Participation of the personnel, particularly the physicians, in the data collection during both surveys and in the AP recommendation co-creation were low. Theimplementation of AP recommendations led to undesired consequences, AP-related stress. It

probably weakened the AP recommendation acceptance and adherence in the study hospital OT. The possibility to apply advanced methods in analysing the quantitative survey data was limited or barred due to the low survey response rates. The lack of AP-related intraoperative documentation distorted the initial focus of the study.

During the evaluative development of the intraoperative APs, it was found useful to critically inspect the competence of the evaluator. According to Patton (1990), the researcher should be well-informed and familiar with the evaluated environment and programme. It was crucial that the observer as an evaluator possessed personal experience of the performance observed. The competence of the evaluator (T.-K. A.) was introduced in “Ethical aspects" (pages 66-70), according to evaluative ethics (Newman & Brown 1996).

Following the ideas of Patton (1990), it was considered important that all the members of surgical personnel participating in the data collection agreed on the focus of the evaluation. By this, it aimed to ensure that the quality of solutions made during the evaluation depended more on an experience than behaviour.

6.4.1 RELIABILITY AND VALIDITY OF THE SURVEYS MEASURING ACCEPTANCE OF AND ADHERENCE TO ASEPTIC PRACTICE RECOMMENDATIONS (III)

This study aimed to investigate the acceptance of and adherence to APs among OT personnel before and after documenting evidence-based intraoperative AP, and 12 years after the documentation by the follow-up survey. Before the AP recommendation co-creation, national AP recommendations existed at a very general level, and the concept validity of AP and its sub-concepts was limited (Grove et al. 2013). Some detailed local AP recommendations existed in the study hospital OTs focusing on specific operations, like orthopaedic prosthesis and gynaecological operations. Many AP practices are learned and performed according to varying implicit knowledge from older generations to the younger ones. This probably hampered the abilities for AP self-evaluation among the OT personnel (Evans et al. 2002). Some of the intraoperative AP guidelines and recommendations, like surgical site disinfection, had rival procedures in the ongoing search for evidence and cost-effectiveness (Parienti et al. 2002; Al-Naami et al 2009; Magalini et al. 2013). This may reduce the content validity of the AP recommendations.

In the study and comparison hospitals, the AORN (1991 & 1999) recommendations were used as cornerstones for the development of criterion-referenced AP assessment and testing the evidence-base for intraoperative APs. We implemented them aiming to improve the concept validity of the measured APs in measuring the acceptance of the evaluation criteria (Evans et al. 2002). The AORN 1991 recommendations were used for the first time in 1995-1996 observations and in giving feedback for the personnel in both hospitals (Liljeblad 1997). After all, the AORN recommendations were largely

unknown among both the study and comparison hospital OT nurses. The knowledge used in the AORN recommendations were based on traditional practices and expert opinions of the personnel performing intraoperative AP. Only a few evaluative observations were reported in testing the recommendations (Crow & Taylor 1983; Radke & Ford 1993). This made the quality assessment of the methods used, like the traditional reliability analyses, challenging (Baartman et al. 2007).

The reliability and validity of the three surveys (III) were aimed to be reached by careful data collection, information given to all the respondents and by using a questionnaire with items formulated according to AORN (1991 & 1999) recommendations (Evans et al. 2002). The AP incidences found critical during the observational study in both study and comparison hospital OTs in 1996 were used in the formulation of the survey questions. The primary questionnaire constructed during the planning phase of the evaluative programme before the documentation of the local AP recommendations. The items on the questionnaire were not introduced according to the initial AP model. After the pilot survey (n=22) in the third hospital of the university hospital district, the face validity of the questionnaire was improved. The wording of some statements describing the practical performance of AP was improved. The AORN recommendations updated in 2013 were introduced in the 2013 follow-up survey according to the initial AP model.

The participation of the OT professionals decreased during the study (III) challenging both the reliability and validity of the results, even the generalisability theory was not used (Robson 1995). Despite all the challenges, it was possible to measure the acceptance of and adherence to AP recommendations among 52 professionals participating in the surveys. This improved the stability reliability of the scales used (Grove et al. 2013). The results reported by the 52 respondents indicated critical incidents, like the needlestick injuries, as important triggers for recommendation adherence. Due to the deep commitment to the recommendation co-creation and to the qualitative study process among OT nurses in the study hospital, it was possible to achieve copious qualitative data supporting the conclusions made from the quantitative data. This improved the content validity of the intraoperative AP recommendations (Grove et al. 2013).

The non-parametric distribution of the data collected in all three measurements restricted the use of explorative factor analysis in the reduction of the variables used as meaningful evaluative tools. Grouping the summation variables by the mean operator served as a practical method for construction of the instruments measuring the acceptance of and adherence to the local AP recommendations. The low number of respondents did not allow for the best possible use of the initial AP model (Figure 2, P. 53) in the construction of the assessment tools. Many recommendations not included in the evaluation tools and the thresholds for acceptance of and self-reported adherence to the AP recommendations were not set for the same reason. The consensus of

participants concerning the focus of the evaluation (the intraoperative APs) was assessed by measuring the scale reliabilities by Cronbach α values for internal consistency of the scales (Glenister et al. 1991; Patton 1990 & 2011).

Table 25 Differences between acceptance and adherence to self-reported aseptic practice recommendations.

Recommendation		Paired differences		
	Mean (SD)	Mean (SD)	Spearman's rho (p=)	Wilcoxon Signed Ranks test Z (p=)
I don't don sterile gown outside OT	3.87 (0.423)	0.167 (0.826)**	0.280 (0.023)*	-2.134 (0.033)* [c]
Sterile gown not worn outside OT	3.76 (0.556)			
I change soiled surgical attire during work day	3.71 (0.607)	0.652 (1.143)**	0.82 (0.514)	-4.031 (0.000)* [c]
Sterile attire heavily contaminated with blood changed	3.11 (1.040)			
My arms extended gloves cover cuffs of sterile gown	3.78 (0.760)	-0.108 (0.886)***	0.14 (0.251)	-1.078 (0.281) [b]
Cuffs covered by gloves totally	3.89 (0. 472)			
During operation I discuss operation-related issues only	2.41 (0.784)	-0.606 (1.162)**	0.103 (0.411)	-3.692 (0.000)* [b]
Intraoperative conversation aseptically important	3.02 (0.903)			

* Statistically significant at the 0.05 (2-tailed); ** n=66; *** n=65, b=based on negative mean ranks; c=based on positive mean ranks

In clinical performance assessment, there is a possibility for the scoring of potential or ideal, rather than actual, performance (Evans et al. 2002). This possible bias was assessed by measuring the criterion validity for the survey statements. The mean values for the acceptance of the AP recommendations were compared with the mean values for the self-reported AP recommendations adherence between four pairs of statements (Table 25). The Spearman correlations between the non-parametrically distributed ordinal-level variables were computed. Wilcoxon signed-rank tests were conducted to measure the mean differences between statements. For all analyses, results yielding a $p < 0.05$ were considered statistically significant.

In the initial evaluation phase, before the AP recommendation documentation, the importance of the active voice of the respondent in the statement formulation was recognised important to study. During the

development work, it was found interesting to evaluate the differences in self-reported acceptance of and adherence to the intraoperative AP recommendations (Aholaakko & Metsälä 2018). Four pairs of statements found to measure both the acceptance of AP recommendations and self-reported adherence to AP recommendations.

The correlations between the four pairs of statements varied from 0.10 (p=0.411) to 0.82 (p=0.514). The only statistically significant correlation was found between the acceptance of and adherence to the recommendation for not donning sterile gowns outside the OT. Wilcoxon signed ranks tests between the four pairs of recommendations found statistically significant differences in mean values for not donning the sterile gown outside OTs, changing heavily-contaminated sterile attire, and considering intraoperative conversation aseptically important. These comparisons indicate that the acceptance of AP recommendations did not necessarily report the clinical adherence to AP recommendations. The results of the stimulated recall interviews (I) revealing the AP performance producing stress support these initial findings. In future survey questionnaires, it is crucial to find and use the best possible formulations in questions evaluating clinical AP in the most reliable way.

6.4.2 RELIABILITY AND VALIDITY OF THE STIMULATED RECALL INTERVIEW STUDY ABOUT ASEPTIC PRACTICE-RELATED STRESS (I)

The reassurance of the clinical relevance and conceptual validity of the observed intraoperative APs was considered useful to perform in several phases of this evaluative development project (Patton 1990). The validity and reliability of the observed data was tested by using both qualitative and quantitative methods.

The international AP recommendations (AORN 1991 & 1999) were validated clinically during the co-creation of the intraoperative AP recommendations with the assistance of the primary survey results. The evidence-based local intraoperative APs were saved to the intranet of the study hospital for clinical use in 2001. The constructed local AP recommendations were returned to the empirical world with the assistance of the stimulated recall interview feedback about the video-recorded intraoperative APs during the breast operations (Baker 2004). The qualitative data collection methods, stimulated recall interviews and feedback for circulating nurses by peer-review of performed APs were implemented in describing and validating the intraoperative APs in the study OT.

When using the video-recorded observation as a method of data collection, it was possible to take into consideration situational factors in the performance of intraoperative AP (Patton 1990, 25). The circulating nurses interviewed acted as participating observers, validating the observational results when collecting the intraoperative AP-related data as part of their everyday work.

The local AP recommendations were found to be clinically relevant during the personal and structured feedback for circulating nurses. During the stimulated recall interviews, the circulating nurses as interviewees served as their own controls, validating their own APs (Baker 2004; Peräkylä 2004). The interviewer (T.-K. A.) confirmed her assumptions and conclusions during the interviews. This possibly improved the reliability of the data collection, and facilitated revealing the objective perspectives of AP as well as possible (Baker 2004; Peräkylä 2004). The interviewer is a healthcare educator with experience in coordinating AP-related continuous quality programs in the study surgery since 1996. The respondents spoke openly, authentically and truthfully to a person they knew. This may have influenced the data generation from internal and external state-of-affairs viewpoints (Baker 2004).

6.4.3 RELIABILITY AND VALIDITY OF THE SURGICAL SITE INFECTION STUDY (II)

The understanding of the everyday routines of circulating nurses as factors connected to SSIs increased the motivation to collect the data precisely and competently. It also led us to modify the initial research questions to achieve relevant and valid results. The lacking or minimal intraoperative documentation of nursing-specific interventions obstructed the testing of the connection between intraoperative APs and SSIs. The experience achieved during this internal validation process was also beneficial in assessing the reliability and validity of the data on the patient records, including all operation-related documents of breast surgery patients in the study exploring the connections between SSI and documented intraoperative APs (II).

The data from patient documents and hospital statistics was collected as a routine part of care. It reflected the conditions, treatments and definitions many surgical professionals completed in clinical settings by Gastmeier et al. (2001). The data was used in defining the SSI rates before and after the AP recommendation documentation. During follow-up studies exploring SSI risk factors, the rate of infections was reported as decreasing due to the research interventions (Gil-Egea et al. 1987; Olson & Lee 1990). The lack of proper documentation of intraoperative APs in both study and comparison OTs disrupted the assessment and reporting of AP performance and its impact on the SSI rates. The focus of the study turned to defining the SSI risk factors in breast operations (II).

Multiple data sources were used to avoid possible lack of consistency and under-reporting causing unreliable judgements (Gomm 2004). Despite all the efforts, missing data led to the exclusion of 22 patients from the SSI risk analysis. The aim was to collect simple and objective data, but the comparability of the results of the study (II) and those reported in the international literature was limited (Gaynes et al. 2001; NNIS 2002; Bunn et al. 2006; Monge Jodrá et al. 2006; Prospero et al. 2006).

In measuring the risk factors for SSIs, making the dependent variable dichotomous for using the backward logistic regression analysis method caused a loss of information. This method is used instead of general logistic modelling to produce reliable predictions for SSI risks due to the non-parametric dependent variable. The formation of dichotomous variables out of the chosen independent variables aimed to improve the reliability of the clinical data (Munro 1997; Gomm 2004). Internationally, the results of the SSI study (II) were used in discussing the high rate of SSI and SSI risk factors in breast surgery by O'Connell and Rusby (2013). According to Olsen et al. (2015), more specific reporting of the relationship between primary versus reoperation would benefit the comparison of international studies.

6.5 RECOMMENDATIONS FOR INTRAOPERATIVE ASEPTIC PRACTICES

The high number of patients suffering from HAIs (Magill et al. 2015) like SSIs demonstrated the demand for a multi-professional approach to enhancing AP adherence. Evidence-based efforts in intraoperative practice to reduce SSIs are well-reasoned. In managing effective IP programmes and cost-effective surgical AP, the barriers to and facilitators for guideline adherence are worth understanding. The results of this developmental evaluation project pointed out clear foci for further development.

To be effective, the AP guidelines need to be well-structured, well-documented, concise, and easily implemented in clinical practice (Burkitt et al. 2009; Cutter and Jordan 2012). The explicit evaluative development of clinical practices includes precise documentation and regular measurements to maintain the acceptance of the personnel and secure high level guideline adherence. The co-created recommendations for intraoperative AP based on the AORN (1991 – 2013) recommendations focus on the AP of surgical team members. They may serve as a baseline and starting point for future co-creation processes.

In the future it is important to construct AP recommendations during an interdisciplinary evidence-based process and implement them carefully to guide the work of all surgical professionals. It is also important to complete the development and implementation of the guidelines according to evidence in a cost-effective manner (Patton 2011). Being aware of and believing in the advantages of the guidelines will facilitate the guideline adherence of the surgical personnel (Osborne 2003; Welc et al. 2013).

Achieving guideline adherence requires efficient professional evidence-based education, workplace training and proper infection reporting. In particular, the education of new hires and inexperienced personnel is important (Burkitt et al. 2009; Cutter and Jordan 2004; Welc et al. 2013). The weaknesses in AP due to lack of work experience are possible to improve with the presence of experienced clinical mentors who have guideline-adherent AP

and relevant assessment tools. Having repeated computerised criteria-based AP observations of clinicians (experienced clinicians as well) and occupational injury reports included in daily intraoperative documentation may be beneficial in improving AP adherence.

Intraoperative aseptic practices are recommended to be performed by

1. using clean disposable, disinfected and/or sterile items in a relevant manner
2. preparing the sterile/disinfected field as near to the time of performance as possible
3. preparing the sterile field inside the clean air zone in the operating theatre
4. covering all the skin and hair when working in the sterile field
5. avoiding unnecessary movements in the sterile field, respecting air-current models
6. avoiding unnecessary conversation during the operation
7. avoiding traffic in and out of OT
8. avoiding unnecessary handling of sterile items, drapes and sponges
9. using the hands-free technique with sharp items
10. implementing clean and dirty techniques

Figure 4 Baseline principles for development of intraoperative aseptic practices

The evidence indicating poor intraoperative AP and operations of long duration as potential risk factors for SSI require more detailed investigation (Emori et al. 1991; CDC 2004). To facilite the future developmental evaluation of the intraoperative APs, general AP principles are introduced in Figure 4. They are important to review and test in various clinical settings according to the procedure they will be applied to. The baseline model for intraoperative APs (Figure 5) may serve as a structure for future research and continuous development work nationally and globally. In the future it is important to define and test the critical incidents of the numerous recommended intraoperative APs and focus on testing and developing them as part of evidence based guidelines. The sub-concepts, “Aseptic technique”, “Aseptic behaviour” and “Preparation of the personnel for practicing in the sterile field” have traditionally been on the focus of intraoperative AP, but also the sub-concepts “Preparation and protection of the patient for operation”, “Central services of the equipment used during the operation” and “Environmental services”, as well as the least studied phase of the intraoperative AP, “Disestablishment of the sterile field”, require careful investigation and definition of their role in infection prevention and control during the intraoperative phase of the operation.

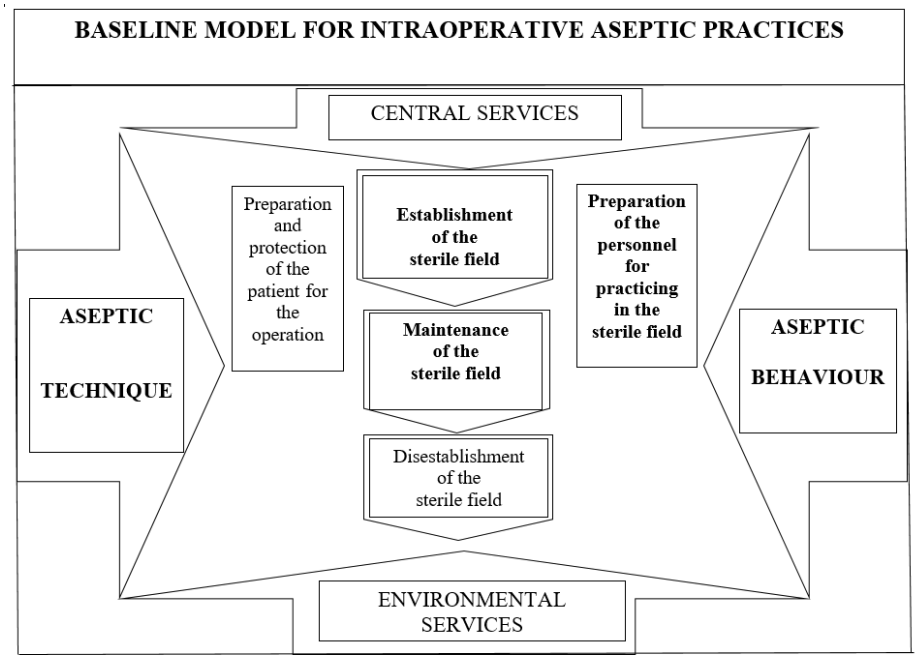

Figure 5 Baseline model for development of intraoperative aseptic practices.

7 CONCLUSIONS

1. The varying acceptance of and adherence to the intraoperative AP recommendations requires improvement.

2. Stress due to the challenges of implementing the AP recommendations is avoidable by interprofessionally co-created evidence-based APs.

3. The re-operations, drainage and obesity was found SSI risks in breast operation, antimicrobial prophylaxis may be considered in these patients.

4. Assessment of intraoperative IP is possible to improve by including the baseline model for intraoperative APs and relevant criteria in the documentation.

5. Carefully planned and implemented projects are necessary in improving the evidence-based recommendations for intraoperative AP to secure the safety of the surgical patients, personnel and environment.

6. The expertise of the personnel is important to develop through participative and strategic training and structured follow-up reporting.

7. It is beneficial to combine the limited resources for continuous developmental evaluation of the intraoperative AP.

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Appendix 1 Aseptic zones in Operating Theatre

Aseptic zone	**Characteristics of aseptic practice**	**Level of supervision**
Operating field	***Preparation of personnel:*** * non-linting OR attire * clean mouth and nose cover / helmet * non-linting clean/disposable hair cover * surgical hand scrub of personnel * sterile gloves, gown 5 cm above elbow and from chest to sterile operating or instrument table level ***Preparation of the patient:****disinfected patient skin or mucosal membranes ***Central services:****sterile instruments, drapes and other barriers, liquids, equipments ***Environmental services:*** * immediate spot-disinfection * conventional ventilation: a degree of turbulence inevitable by near the ceiling air introduction * ultra clean ventilation: unidirectional HEPA-filtered air discharge provided from 2.8 x 2.8 m filter bank or diffuser positioned over the sterile operating field *lightning providing adequate illumination to surgeon by attention to aerodynamic properties contributing air quality ***Aseptic technique:*** *sterile barrier materials in table level considered as sterile * sterile instruments, equipments and barriers considered as contaminated after exposure to cancer cells * patient skin contacts by sterile gloved hands recommended to kept in minimum ***Aseptic behaviour:*** * one-day-use of OR attire * limited traffic patterns * limited discussions * limited mucosal membrane contacts * improved hand disinfection	* under continuous supervision by direct eye contact * no compromises allowed * limited permission only for adequate personnel and visitors
Sterile field = *the operating field, sterile instrument table, sterile gown and primary sterile barriers*	*** ***Preparation of personnel:*** * cean non-linting OR attire * clean mouth and nose cover / helmet * clean/disposable non-linting hair cover *surgical hand scrub of personnel* sterile gloves * gown sterile 5 cm above elbow and from chest level to sterile operating or instrument table level	*under continuous supervision by direct eye contact *no compromises allowed *breaks by air, droplet, hand, blood and body fluids contamination originating

	Preparation of the patient: *disinfected patient skin or mucosal membranes ***Central services:*** *sterile instruments, drapes and other barriers, liquids, equipments ***Environmental services:*** * immediate spot-disinfection *conventional ventilation: a degree of turbulence inevitable by near the ceiling air introduction *ultra clean ventilation: unidirectional HEPA-filtered air discharge provided from 2.8 x 2.8m filter bank or diffuser positioned over sterile field *lightning providing adequate illumination to surgeon by attention to aerodynamic properties contributing air quality ***Aseptic technique:*** *sterile barrier materials in table level considered as sterile * patient skin contacts by sterile gloved hands recommended to kept in minimum * sterile instruments, equipments, instrument table areas and barriers considered as contaminated after exposure to cancer cells ***Aseptic behaviour:*** * one-day-use of OR attire * limited traffic patterns * limited discussions * limited mucosal membrane contacts * improved hand disinfection	from sterile field should be assessed for recreation of sterile field * limited permission only for adequate personnel and visitors
	***	
Sterile barrier field = *areas out side operating and sterile fields, draped areas and sterile instrument tables under the table levels, back and arms above elbow of sterile gown*	***Preparation of personnel:*** * clean non-linting OR attire * clean mouth and nose cover / helmet * non-linting clean/disposable hair cover ***Preparation of the patient:*** *disinfected patient skin or mucosal membranes ***Central services:*** *sterile instruments, drapes, liquids and equipments in sterile field *conventional ventilation: a degree of turbulence inevitable by near the ceiling air introduction *ultra clean ventilation: unidirectional HEPA-filtered air discharge provided from 2.8 x 2.8 m filter bank or diffuser positioned over sterile field ***Environmental services:*** * immediate spot-disinfection * a degree of turbulence inevitable ***Aseptic technique:*** *sterile barrier materials under table level	*not supervised continuously by direct eye contact, *unintended breaks by air, droplet, hand and blood and body fluids contamination do not require recreation of sterile field * limited permission only for adequate personnel and visitors

	considered as contaminated *back and low areas of sterile gown considered as contaminated ***Aseptic behaviour:*** * daily change of non-linting OT attire * limited traffic patterns * limited discussions * limited mucosal membrane contacts * improved hand disinfection	
Aseptic zone out side sterile barrier field	*** ***Environmental services:*** * immediate spot-disinfection *<u>conventional ventilation</u>: a degree of turbulence inevitable by near the ceiling air introduction ***Aseptic behaviour:*** * daily change of non-linting OT attire * clean/disposable non-linting hair cover * limited traffic patterns * limited mucosal membrane contacts * improved hand disinfection * opening and closing of doors should be kept in minimum to avoid turbulent air currents	* limited permission only for adequate personnel and visitors
Clean zone ***Protected zone*** ***Disposal zone***	*** ***Environmental services:*** * immediate spot-disinfection ***Aseptic behaviour:*** * daily change of non-linting OT attire * limited traffic patterns * limited mucosal membrane contacts * improved hand disinfection	* limited permission only for adequate personnel and visitors

Appendix 2 Acceptance of the aseptic practice recommendations for scrub nurse working in the sterile field.

Recommendations for scrub nurse working in the sterile field (n=63)	Mean (SD)
Sterile field constantly supervised *	3.84 (0.410)
Number of persons in OT limited during operation *	3.78 (0.490)
Sterile instrument table not established outside OT # *	2.75 (1.177)
Sterile field not established one hour before operation # *	3.21 (1.050)
Sterile item not tossed into the sterile field # *	3.57 (0.689)
OT doors kept closed during maintenance of sterile field *	3.79 (0.408)
Sterile gown not worn outside OT # *	3.71 (0.607)
Hands completely dry before gowning *	3.37 (1.168)
Handling sterile gown inside only during gowning *	3.89 (0.406)
During gowning gloves not tossed on the sterile gown # *	2.97 (1.107)
Gown cuff contaminated if hand visible outside *	3.67 (0.783)
Scrubbed person does not tie sterile gown laces oneself #	3.63 (0.725)
Gloves touched after gowning only *	3.40 (1.025)
Sterile gloves not worn over the main instrument table # *	3.21 (1.109)
Both back and front sides of sterile gown not sterile # *	3.52 (0.877)
Gown sleeves considered sterile from 5 cm above elbow to the cuff*	3.03 (1.047)
Sterile gown sterile from the chest to the level of the sterile field *	3.84 (0.410)
Neckline, shoulders and axillary gown regions contaminated *	3.49 (0.896)
Closed assisted gloving method used to glove team members *	2.75 (1.077)
Gown cuff covers fingertips during assisted gloving *	2.94 (1.216)
Cuffs covered by gloves totally *	3.89 (0.479)
Unscrubbed person not moving between two sterile fields *	3.67 (0.596)
Scrubbed person not seated while waiting # *	2.16 (1.050)
Seated scrubbed person not keeping hands under waist level # *	3.25 (1.015)
Scrubbed person not visiting outside OT during operation # *	3.32 (0.839)
Two scrubbed persons turn face to face or back to back *	3.63 (0.848)
Unscrubbed person keep 50 cm distance from sterile field	3.51 (0.821)
Two persons not handling sharp objects simultaneously * **	3.70 (0.687)
Sharp and heavy objects presented onto sterile field *	3.35 (1.034)
During draping material kept compact # *	2.16 (1.066)
During draping not reaching over unsterile area*	3.90 (0.346)
Items over sterile field covered with sterile barrier *	3.10 (1.027)
During draping material kept over waist level # *	3.43 (0.928)
Draping distally from wound area *	3.75 (0.671)
Only the top surface of a sterile draped area considered sterile *	3.81 (0.618)
During draping sterile gloves protected *	3.35 (1.034)

Suction tubing secured with non-perforating device	3.92 (0.346)
Not checking diathermia electrode after draping #	2.71 (0.888)
Sterile field covered with a sterile drape during x-ray imaging *	3.51 (0.738)
Fixed sterile drapes not moved *	3.78 (0.419)
Patient's skin re-disinfected after adhesive drape removed	3.37 (0.938)
Double gloving when expected exposure on infected material *	3.57 (0.856)
Indicator gloves taken for risk-operations *	3.95 (0.215)
Sterile gloves inspected for integrity before operation starts *	3.87 (0.553)
Sterile gloves changed after suspected or visible defect *	3.98 (0.126)
Sterile gloves changes after every procedure *	3.98 (0.126)
Sterile gloves inspected for integrity during operation *	3.90 (0.296)
Sterile gloves changed after touching helmet, visors or hoods *	3.51 (0.896)
Sterile gloves changed after contacting methyl methacrylate*	3.49 (0.859)
Sterile gloves changed after adjusting optic microscope eyepieces*	3.21 (1.003)
Sterile gloves changed every 90 to 120 minutes*	2.46 (1.013)
Swell, expand and loose on hands sterile gloves changed*	3.76 (0.615)
Hands disinfected immediately after removing sterile gloves *	3.86 (0.396)
Sterile attire heavily contaminated with blood changed *	3.11 (1.049)
Entire sterile set changed if hair or other organic material found *	3.81 (0.592)
Entire set changed if instrument clamped closed found *	2.75 (1.107)
Instruments used in gastric, bowel and perineum area isolated *	3.56 (0.757)
Intraoperative conversation aseptically important #	3.00 (0.916)
Scale mean	3.44
Cronbach's α-reliability coefficient of the 58 item scale	0.824
# Items reverted into 4-point scoring so that higher numbers represent stronger agreement to the recommendations; * Appears in 2013 updated AORN recommendations	

List of tables, figures and appendixes:

ORIGINAL PUBLICATIONS

I

JCN Journal of Clinical Nursing

Journal of Clinical Nursing

CLINICAL ISSUES

Reducing surgical nurses' aseptic practice-related stress

Teija-Kaisa Aholaakko

Aims and objectives. This paper aims to explore aseptic practice-related stress in surgery. The objectives are to define stress-related factors and the means to reduce the stress.

Background. Occupational stress is related to personal characteristics: job satisfaction and physiological and psychological well-being. The stress symptoms are often classified as part of a negative mood. Nurses have expressed stress when deadening their conscience to external demands with co-workers or internal working role-related demands. Surgery nurses expect fair division of work and compliance with rules. The hospital management, technology and the medical profession, instead of the needs of the patient, are recognised as a danger in the development of surgery nurses' role.

Design. A qualitative stimulated recall interview was performed in the surgery of the university hospital.

Methods. Thirty-one operations were videotaped, and 31 nurses interviewed during videotape stimulation. The 1306 text pages were transcripted and analysed by a qualitative membership categorisation device analysis.

Results. The analysis revealed aseptic practice-related stress which constructed a sixteen level category. The membership categorisation identified connections between qualitatively attributed personnel and seven stress factors: working experience; time; equipment; person; patient; working morals and power. Final analysis revealed nurses reducing aseptic practice-related stress by safe, peaceful, competent and relative means.

Conclusions. The aseptic practice-related stress varied from positive motivating feelings to exhaustion. The stress was experienced by medical and nursing co-workers and reduced by means which varied according to expertise and co-workers.

Relevance to clinical practice. This study showed needs for both the shared multiprofessional documentation of aseptic practice and better adherence to recommendations. Constructive means are useful when solving conflicts and replacing person-related aseptic practice with evidence-based. They may support nurses' professional growth, reduce their stress and increase the surgical patient's safety.

Key words: aseptic practice, clinical research, nursing, occupational stress, operation, stimulated recall interview, surgery

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Introduction

The stress that surgery team members experience is defined as one of the biggest challenges to be overcome to maintain collaboration and good patient care (Silén-Lipponen *et al.* 2002). Surgery nurses experienced the stress because of difficulties; uncertainty and changes when organising work during emergency situations; in conflict situations because of insufficient flow of information (Silén-Lipponen *et al.* 2002); lack of time; and medical domination (McGarvey *et al.* 2004, Flin *et al.* 2006). They pointed out the importance of patient safety, fair division of work and compliance with rules when controlling the work-related stress in surgery (Silén-Lipponen *et al.* 2002, Flin *et al.* 2006).

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Killen (2002) considered non-compliance with aseptic practice (AP) in surgery as a stressful moral dilemma reflecting a system-wide problem. AP is defined as a means of minimising wound contamination by ensuring the sterility of equipment and items in the sterile field during invasive procedures (AORN 1999). In international studies, the compliance with infection control precautions is usually reported to remain suboptimal (Larson & Kretzer 1995, Pittet *et al.* 2000, Reilly *et al.* 2002, Flin *et al.* 2006), but Finnish nurses reported performance of AP as one of their strongest professional skills (Räisänen 2002, Tengvall 2010). To investigate the gap between the attitudes and compliance with AP, some Finnish nurses have performed quality improvement projects. In the study surgery, AP has been developed in the contexts of: (1) preparation of the personnel and (2) preparation of the patient for the operation; (3) central services; (4) environmental services; (5) aseptic behaviour and (6) aseptic technique during creation, maintenance and discharge of the sterile field.

Background

In the findings of Stone *et al.* (2004), the occupational stress was found related to: personal characteristics; job satisfaction; physiological and psychological well-being. The stress symptoms were often classified as part of negative mood states, and people who were sensitive to punishment but not sensitive to rewards were more prone to stress (van der Linden *et al.* 2007). Nurses have reported stress when they had to deaden their conscience relating to external demands to be able to collaborate with co-workers or internal demands to uphold identity as 'a good healthcare professional' (Silén-Lipponen *et al.* 2002, Juthberg *et al.* 2007). The hospital management, technology and the medical profession, instead of the needs of the patient and the principles of nursing, were recognised as a danger in the development of independent surgery nurses' role (McGarvey *et al.* 2000) and professional performance of it (McGarvey *et al.* 2004, Flin *et al.* 2006).

Sørlie *et al.* (2005) found that nurses created self-demand in hectic and stressful care; worked alone; felt frustration owing to time, organisation and divided tasks and responsibility for patients' well-being. In surgery, nurses had working hours and workload-related stress, and challenges were focused on physical patient care or on cognitive issues (Hjort Jacobsen *et al.* 2006). Long working hours was defined as a contributing factor for chronic fatigue syndrome among healthcare workers (Kara *et al.* 2008). On-call work as a stressor caused fatigue-related errors, low mood, tension, frustration, depression and anxiety (Nicol & Botterill 2004). Flexibility allowed a surgery to be run with the smallest possible number of staff members and was more important than delivering 'good care' (McGarvey *et al.* 2004).

When controlling their stress, nurses were seeking assistance for physically diverse work from others (Sveinsdóttir *et al.* 2007) and they felt positive about team work (Silén-Lipponen *et al.* 1999, 2002, Sørlie *et al.* 2005). Both physical and emotional resources were found to be important stress buffers (van den Tooren & de Jonge 2008). Support from peers was considered to be essential close to suffering patients in surgery (Torjuul *et al.* 2007). High-decision authority; work predictability; support from supervisors and skill discretion predicted significantly reduced numbers of absence days (Nielsen *et al.* 2004).

Stacciarini and Tróccolli (2003) found that constructive thinking and job satisfaction were inversely associated with occupational stress among nurses. Surgery nurses expressed empathy, flexibility and caring to ensure positive experiences for patients. They used ethical conscience and clinical management to prevent or resolve conflicts, and constructive management techniques to direct attention away from budding conflicts (Chard 2000, Espin & Lingard 2001, Sigurđsson 2001, Riley & Manias 2002). Finnish surgery nurses perceived collegiality, ability to organise and anticipate work in open communication, and confidence in others' professional skills as demands of multiprofessional collaboration (Silén-Lipponen *et al.* 1999, 2002).

Björn and Lindberg Boström (2008) found that nurses use the knowledge of a surgeon's personal ways to work and act when solving problems during an operation. Some nurses perceived looking after the surgeon as one of their responsibilities. They identified the nurses' choice 'Keeping happy and not upsetting the surgeon' as a hostess role accomplished by talk and action (Timmons & Tanner 2005). Richardson-Tench (2008) criticised nurses for rejecting accountability for the patient by having a familiar relationship with surgeons and reducing the surgeon's stress by 'social chit-chat'. Silén-Lipponen *et al.* (2002) and Killen (2002) both reported surgery nurses being stressed because of the authority of surgeon. According to Killen (2002), it sometimes made it impossible for the nurses to follow the professional standards in AP. This led to suboptimal care; the surgeons continued the operation without proper consideration of potential complications. Both studies reported that assertiveness was needed when the nurses solved working-morals-related problems for the benefit of the patient.

This study aims to explore AP-related stress among surgery nurses. The objectives are to define stress-related factors and the means to reduce the stress experienced by supervising circulating surgery nurses (SNs). The specific study questions:

1 How did the SNs define the AP-related stress during breast operations?
2 What were the AP-related stress factors during breast operations?
3 How did the SNs reduce the AP-related stress during breast operations?

Methods

Design

This qualitative study was performed as stimulated recall interviews of SNs to describe and explain the social conditions under which AP as organisational work was and was not done effectively during surgery. As is typical for a qualitative method, the focus of the study was clarified during the research procedure: during the interviews, the performance of recommended AP showed to be a source of stress for SNs. This study answers questions about the how and why of organisational outcomes of AP-related stress and the means of reducing it. The study provides an inside standpoint to reveal possible unintended consequences of recently documented AP policies and procedures in one surgery. It contrasts the outside perspective with the inside perspective when focusing on the details of surgery professionals' shared organisational knowledge, their everyday actions and multiprofessional interaction in performance of AP (Miller *et al.* 2004).

With this approach, it is not the interview that is good or bad, but the ability of the analysis to explicate the routine grounds of the work. The interviewer and the respondent together assign the meaning to the interiors and exteriors they discuss (Baker 2004). When the interviewees were considered as interiors, it was crucial to understand their role and responsibilities. In the study surgery, nurses worked in varying roles: as members of anaesthesia teams, recovery room teams or in two roles in surgical teams. Usually they changed teams weekly or daily when needed to be flexible. In the surgery team, the nurses varied their roles so that in every other operation, they worked as a 'scrub nurse', and in every other operation, they 'circulated' and 'supervised' (SN). All the nurses in the study surgery were registered professionals, i.e. why they prefer to call themselves 'supervising nurses' rather than 'circulating nurses'. In SN's role, in addition to traditional circulating nurses' tasks, the criteria and evidence-based assessment; supervision; and documentation of AP were important parts of the work. In the study surgery, the SNs considered themselves as important and permanent members of the surgical team, not assistants.

Data collection

The data were collected from February–June 2003 in one surgery department of Helsinki University Central Hospital (HUCH). The stimulated recall interview was offered to all 34 nurses in the study surgery during breast operations. Thirty-one nurses participated, two refused and one did not work as SN.

Thirty-one operations were videotaped as 3358 minutes of visual data. The recordings started when the nurses created the sterile areas and ended when they discharged them. The videotaped time per operation varied from 42–213 minutes (mean 108 minutes). The stimulated recall interviews of SN were audiotape-recorded one or two days after videotaping.

During the data generation, the researcher performed all the data collection, transcription and analysis. Before the SNs were interviewed, the videos were looked through and the performance of AP was assessed by a semi-structured form. In this form, the criteria for AP were culturally validated and detailed from AORN (1999) recommended practices by the researcher and the personnel of the study surgery together. The videotaped operations (1) provided the interviewee with a stimulus of the original situation; (2) improved the reliability of the data collection and (3) constructed a context and situation for clinical education (Jokinen & Pelkonen 1996, Peräkylä 2004). In the interviews, the SNs analysed the AP performed during the operation. The interviewer stimulated reflections by asking questions like: 'Please, tell me what is important in AP in this situation?', 'Why did you behave like you did?', 'How did you feel?' and 'How did you manage with the stressful situations?' The interviewees performed as their own controls so the interviewer confirmed her assumptions and conclusions during the interviews. By this, the aim was to improve the reliability of the data collection and to reach as objective an inside and outside perspective of AP as possible (Baker 2004, Peräkylä 2004). The interviewer, a healthcare educator, has coordinated the AP-related quality programmes in HUCH surgeries since 1996 including an observational assessment with a laser particle counter.

All but two of 31 stimulated recall interviews were technically possible to transcript. The data consisted of 1306 text pages in Arial 11 font with single-line spacing. All interviews were transcripted verbatim. The pauses during interviews were identified by three periods (…). The feelings of interviewees were interpreted during the operation and recordings and written in parenthesis (like uncertain, frustrated and worry). The noises in surgery made the transcription challenging.

Ethical considerations

The acceptance for this study was given by heads of HUCH and the ethics board of HUCH district. Nurses were informed personally. They were keen to discuss the performance of AP so the atmosphere in the study surgery was open. Written permission to videotape the operations was received from all patients after verbal and literal information. The signed consent was saved in patients' records. Patient anonymity on videotape was ensured according to the demands of the ethics board. All physicians were informed via e-mail and personally. The final acceptance for videotaping was ensured verbally in the beginning of every operation from the patient and all the team members.

Analysis of the interview data

The interview text of seven SNs was analysed during a primary analysis. After reading the text, 'a membership categorisation device analysis of interview talks' introduced by Baker (2004) was applied. As a result of the holistic impression, the AP was constantly present in the surgery. In their talk, the SNs identified stress as not necessarily a negative attribute of the AP, but as a meaningful and important factor in performance of AP. This guided us to follow Baker's advice to reveal both the hidden and visible AP-related stress. In the primary analysis, it existed on eleven levels: desire, experience, need, discomfort, problem, worry, uncertainty, frustration, tension, pressure and fear. The primary membership categorisation identified surgeons, patients and nurses of surgical wards and emergency room; and younger, senior and student nurse colleagues in surgery as stress-related 'members' of breast operations. The analysis revealed that competence rather than working years was important in stress management. The AP-related stress was worked through to look at the categories and attributions connections that members produce to find the 'courses of social action' in stressful situations. Time, equipment, person, patient, working experience, morals and power were identified as the attributions of stressful AP situations. The cultural validation for the primary findings was carried out with the whole nursing personnel of the study surgery during an interactional presentation of the categorical results before the final analysis.

Table 1 The themes of stressful aseptic practice (AP) situations and number of units of analyses concerning AP-related stress and means to reduce the stress

The themes of stressful AP situations	Pages of text/number of units of analyses
Working-morals-related stress	93/353
Person-related stress	69/380
Working-experience-related stress in general	63/208
Process of professional growth	5/62
Characteristics of competence levels	16/217
Equipment-related stress	40/193
Time-related stress	26/119
Power-related stress	36/130
Patient-related stress	10/29
Physical stress	2/15
The means to reduce the AP-related stress	95/396

During the first phase of the final analysis, all 1306 pages of text were read carefully. In the text, the description of stress, the cause of stress and the means to reduce stress were usually close together. The analysing units included them all (Table 1). In the second phase, the reduced text was analysed, including the analysing units only by themes and contents. A document file was created for each of the eight themes; seven files on the attributions of stressful situations in AP: 'working experience'; 'time'; 'equipment'; 'person'; 'patient'; 'morals' and 'power', and the eighth theme on 'descriptions of means to reduce stress' in the AP. The expressions concerning stress were recorded within the descriptions in all eight thematic files. The primary descriptions were enriched during the final analysis. In the 'working experience' theme, nurses brought into the discussion one more dimension 'the demands' as experiences of external expectations. It was distinguished from 'the needs' as an internal source of mainly positive stress to perform AP. In the 'morals-related stress' theme, some nurses felt 'guilty of' AP mistakes and blamed themselves for surgical-site infections. Experiences of 'disrelish' and 'exhaustion' were identified as descriptions of extreme stress (Fig. 1). It existed, for example, in the 'power' theme when a nurse had to act against one's professional morals because of a co-worker's extremely unconcerned AP. During the analysis, a new theme, 'physical stress', was identified within the 'patient-related stress' theme.

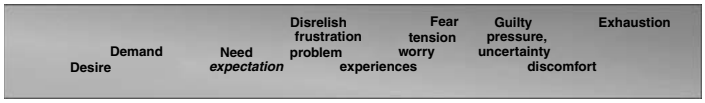

Figure 1 The aseptic practice-related stress in the talk of surgery nurses.

During the third phase, the thematic files were reduced and coded as the content classes. In the 'person' theme, some nurses made visible the profession-specific assumption that 'nurses perform better AP than surgeons'. During the stimulated recall interview, this assumption was not verified. Then, SNs explained lapses in AP by personal and gender-related variations in AP. After this finding, the meaning of collective assumptions as cultural attributes became more visible, and more AP-related assumptions were identified in the study surgery (Table 2).

In the fourth phase, 'the socially particular' AP-related stress was emphasised by defining the membership categories and the means to reduce the stress (Tables 3 and 4). The AP-related stress factors were classified according to surgery team membership with qualitative attributes like 'fussy nurse colleague' or 'the whole surgery team' (Baker 2004, p. 164). Next, the generic means to reduce the AP-related stress were identified among all themes and all membership categories. This was done to reach the abstraction level which made visible the culturally particular description of AP-related stress and the means to reduce it during breast operations.

Results

Of the nurses who participated in the study, 28 were women and three men. They were between their 20s and 60s and had working experience from two months up to more than 30 years in surgery. All nurses had at least first-level registered nurse qualification and a range of other educational and clinical qualifications. As this was a qualitative study, statistical representativeness and generability were not sought.

AP-related stress

In the analysis of the SN's talk, the AP-related stress was categorised as sixteen levels from positive motivating feelings of desire up to extremely stressful situations with exhaustion, feelings of total mismatch of professional and personal demands within the team. The stressful situations in AP identified during the analysis were as follows: 'working experience', 'time', 'equipment', 'person', 'patient', 'morals' and 'power' (Table 3).

In the SN's experiences of AP-related stress, it was possible to recognise competence and working experience–related variation. A senior SN identified stress related to the 'experience' of her co-worker or herself: 'I recognize a kind of competency in behavior of younger colleagues. Say… working experience of two to four years… a kind of feeling of competence is present… and then it bursts like a bubble when you understand things… and when you understand you respect more and are more afraid… competence is not expertise.' A young SN had a desire to perform AP in as talented way as her more experienced colleague. She felt the lack of experience as a threat: '… in spinal-level AP there is a threat that everything is wrong… and in thinking like: 'there is only one way to do things'… Critical thinking is harder.'

A young nurse felt uncertainty because of the run of AP procedures. In situations when there was 'time' available, the pressure to work more was present in the experience of an expert SN: 'From time to time I have a feeling that when you have finished your own schedule, you will have a wonderful bonus operation.' A less experienced SN needed time for the current operation and said: 'All the time the surgery schedule is on my mind. We have to do it during the working day. I am stressed. In my opinion, you should do one operation and

Table 2 General aseptic practice (AP)–related assumptions as cultural attributes during breast surgery

Surgical practice is based on the trust in proper AP of all co-workers (explicit need)
It is impossible to observe AP of co-workers all the time (explicit experience)
It is not possible to realize all AP recommendations literally in real life because of limited space in surgery (explicit experience)
Senior surgeons perform old habits in AP instead of documented AP recommendations (explicit experience)
Junior surgeons learn AP recommendations from surgery nurses (explicit experience)
Novice nurses, junior surgeons, nursing and medical students need more supervision in AP than more experienced professionals (explicit need)
The surgeon is an expert in surgery and surgery nurses in AP (explicit experience)
Limited time resources are part of surgery work but not an excuse for breaks in AP (explicit experience)
Surgery time is expensive (explicit experience)
Saving costs is essential in surgery nursing (explicit experience)
Preparing the next operation during the current one is an effective way to save surgery time (explicit need)
Intact gloves are important part of infection control (implicit need)
Use of hair, mouth and nose cover, and levels in the sterile field are not an important part of infection control (implicit experience)
Novice nurses do not have full responsibility for AP in surgery (explicit experience)
A novice nurse is not in a position to give feedback to a senior colleague (explicit experience)
All members of surgery personnel are experts in AP (explicit experience)

Table 3 Membership categories by sources of the aseptic practice (AP)–related stress during breast surgery

Membership by sources of AP-related stress (numbers of expressions)	
Equipment-related stress (91)	Time-related stress (69)
With a surgeon needing extra sterile supplies	With a surgeon being late
With a surgeon needing personal sterile-supplies	With a waiting surgeon
As a nurse having no training for new equipment	As a nurse practising in a busy situation (faceless member)
As a nurse with sharp items at risk of injury	With too lengthy operating lists (faceless member)
As a nurse decreasing the risk of contamination	
With a novice supervising nurse	
With a surgeon expecting the right instruments	
As a nurse counting instruments	
As a nurse controlling environmental contamination	
Working-experience-related stress (66)	Moral-related stress (48)
As a nurse when a young surgeon dares not ask for help	With a surgeon not performing AP
As senior colleague of a novice nurse in surgery	With a colleague having loose morals in AP
As a colleague of a nurse with a foreign education	As a nurse maintaining own professional know-how
As a novice nurse in surgery	As a surgery nurse in general
As a team member in an expert team	
Person-related stress (47)	Power-related stress (42)
With a hot-tempered surgeon	With a surgeon not performing AP
With a fussy co worker	With a senior nurse co-worker not performing AP
With a co-worker unreceptive to feedback	As a legally responsible professional
With a co-worker disagreeing on AP-related principles	
With a senior surgeon not complying AP recommendations	
When working in different surgery nursing roles	
Patient-related stress (17)	Physical stress (15)
With a patient at risk because of breaks in AP	With a heavy patient
With a patient having potential complications	As a nurse at risk of blood contamination
With a patient as a potential source of contamination	As a nurse at risk because of surgical smoke
With a restless regionally anesthetized patient	As a nurse working in a long operations
	As a nurse using heavy personal protective equipment
	As a nurse working long in same static position
	As a nurse having insistent personal needs during an operation

then concentrate on the other...' 'The pressure to make turnovers faster' was present when one SN tried 'to avoid extra hours after a working day.'

'Equipment' was quite often a source of AP-related stress. Nurses felt worry about breaking expensive equipment during operations or they were stressed about choosing the correct instruments or equipment: 'He says: 'I am not operating with these things…' …and then we change everything.'

The SNs had deep personal feelings and adjusted their AP according to the 'person' they were working with: 'I personally have a more critical attitude with surgeons' AP. And besides this I have to agree, that those who you know to have ... a kind of... aseptic looseness... you pay more attention to... but with those you know, and who have worked long... and you know are responsible... you expect that they work properly...' 'After working a day with (a certain surgeon) you are exhausted because you have to be extra sharp all the time… and despite it… even though you are sharp… you recognize those situations and comment on them… and it does not help at all... So it is depressing.'

The 'patient'-related stress in AP was visible during operations, for example as a need to document the obesity of the patient as a potential risk for infection. A young nurse was worried about harming an old patient's thin skin or had problems with patients' anatomical variances. The poor preoperative preparation of the patient caused nurses feelings of frustration and the restless patient in regional anaesthesia discomfort. 'Physical' work demands were described as heavy and causing discomfort: 'It is heavy to hold the hand of the patient, but you just have to do it!'

'Working'-'moral'-related stress as an open or budding conflict between the surgeon and nurses was often present in the surgery. Some of the interviewees felt very deep accountability for the patient as their moral responsibility. One of the senior nurses described: '… we are accountable for the patient... we have to think on behalf of the patient. Not for

Table 4 Categorisation of generic means to reduce the aseptic practice (AP)-related stress during breast surgery

In-time practice	Exact practice	Safe practice
Practice in good order		
Practice by exact working manners		
Prioritizing practice	Anticipative practice	
Promoting practice		
Preventive practice		
Protective practice	Ensuring practice	
Controlling practice		
Corrective practice		
Time taking practice	Facilitating practice	Peaceful practice
Peacefully practice		
Slowing down practice		
Conflict free practice		
Constructive practice		
Practice with quiet critics	Silent practice	
By silent service		
Silent communication		
Reflective practice	Skilled practice	Competent practice
AP adherent practice		
Sharing practice	Collegial practice	
Respective practice		
Accountable practice	Patient-centred practice	
Participative practice		
Practice with responsible documentation	Responsible practice	
Practice with pertinent feedback		
Practice with critical responsibility		
Practice with pertinent reasoning		
Observative practice		
Position specific active withdrawal	Withdrawal practice	Relative practice
Passive withdrawal		
Accountably withdrawal		
Situation specific practice	Specified practice	
Person specific practice		
Foxy practice		

our own sake… Not for the sake of power and willingness to order. Those things are clearer for us than for the surgeons.'

An SN with some working experience had got stressful 'power'-related feedback after her performance of AP: 'I think that in principal... the surgeon has the final word.' She also had fear of being excluded from the surgical team because of active AP feedback on the surgeon. Additionally, a beginner as a surgery nurse was: '... afraid of making the surgeon angry.' The experiences of being in the focus of power-related decision-making concerning AP were not always related to the experience of the interviewee, and a senior SN had experiences of: 'Surgical field being a battle field.'

The membership categories connected to AP-related stress

The membership categorisation identified 'qualitatively attributed' surgeons; patients; younger, senior and foreign-trained nurses, and student nurse colleagues as stress-related members of a surgery team during an operation (Table 3). Equipment-related stress was connected to a demanding surgeon, novice SN and with SN's own practice as AP specialist being compromised during instrument counts and environmental contamination control.

Members causing time-related stress either were 'face-less', like the rhythm of working, or had faces of a pressing surgeon or SN her/himself. The busy surgery schedule and overall pressure were often experienced as individual feelings of inability to meet the work demands. Working-experience-related negative stress was present when an AP expert worked with junior surgeons or nurses. The stress was felt as positive when an SN worked as an AP specialist 'in a dream surgery team'. Person-related stress was present when a hot-tempered surgeon; fussy co-worker; either nurse or surgeon with limitations on taking feedback or following recommendations for AP participated in the team.

Physical stress was experienced because of heavy patients, existence of patients' body fluids and surgical smoke as occupational risks. Long operations caused stress by static body positions and limitations in taking care of personal needs. Restless patients and the varying roles in a surgery team caused stress. Working morals and power-related stress were experienced owing to co-workers with whom SNs felt it difficult to follow AP recommendations.

Means to reduce AP-related stress

The nurses used situation- and person-specific means to reduce AP-related stress. The chosen means also varied according to the experience of the SN. When stressed by AP-related factors, a competent SN said: 'You should be able to pick up those things which help you to work faster.' A more experienced nurse described her work: 'We always work in a hurry but we must try to work in the right manner and be reasonable…' An expert nurse described means in stress reduction: 'A nurse has to be independent and, sometimes, quite headstrong to have the right to work properly'. A novice nurse solved the budding conflicts in his own way: 'It is better to use the asking-strategy... not to give open feedback ... a little bit like asking: What happened? Did you notice?' He felt professional pride despite limited experience: 'This is a practical profession, so I should think about this with professional pride. So I am able to say after the operation: 'I have done this!' I'll do things with care, because this is meaningful for me.'

The generic means to reduce AP-related stress by safe; peaceful; competent and relative nursing practice were categorised during the final analysis of all stress factors and the membership-related means to reduce stress. 'Safe practice' included exact, anticipative and ensuring performance of AP during an operation. 'Competent practice' was constructed of responsible, patient centred, collegial and a skilled means of reducing stress. 'Peaceful practice' was facilitating and silent. 'Relative practice' included both passive and active withdrawal, and person- and situation-specified means to reduce the stress (Table 4).

Discussion

The goal of the study was objective and credible descriptions of a social world in surgery in the context of AP-related stress. The operations were video-recorded to achieve accuracy and inclusiveness in data collection. The truthfulness of the analytical claims was tested by audio recording the stimulated recall interviews (Peräkylä 2004). The question of 'how much to record' was present in this study during the whole process. The relatively large amount of data made it possible to obtain variation in AP-related stress. For example, the expressions of the pilot analysis were enriched by rare cases in which the surgeon annulled to a great extent nurse's AP or an SN with long working experience was not able to get feedback concerning AP. Without these observations, the social assumptions of AP, as well-organised professional practice based on mutual confidence and acceptance among surgery teams, would be the main result of the study.

As Baker (2004) described, the data were generated, not only collected. The accounts of SNs' answers to the interview questions challenged the cultural assumptions and revealed the reality of AP and team membership in surgery. In this study, the persistent cultural assumption concerning well-performed AP (Räisänen 2002, Tengvall 2010) was compromised. The membership widened beyond the traditional nurse–surgeon relationship. The rich mutual competence-related hierarchy of nurses became visible. The videotaped operations provided both the interviewer and the interviewee with stimuli of the original situation, improved the reliability of the data collection and constructed a possibility to verify the interpretations which the interviewer made during the structured analysis of AP. The interpretations and both the verbal and visible reactions of the interviewees' were discussed during the interviews, transcripted and used during the whole analysing process. In many cases, the interviewees broadly described the situation and justified their behaviour (Jokinen & Pelkonen 1996, Baker 2004, Peräkylä 2004).

The aim of the simultaneous classifications of all themes was the accurate and truthful content for each theme (Peräkylä 2004). In this study, the interviewed SNs described power and working-morals-related stress similarly to the nurses in the studies of Silén-Lipponen *et al.* (2002), Killen (2002) and Flin *et al.* (2006). The accuracy and inclusiveness were difficult to reach between the power and moral themes. Among nurses, the power existed in interaction between experienced and novice nurses, and nurses and medical students. Sometimes, the quality of power was more like professional protectionism to give the best possible clinical education for future colleagues, than the use of hierarchical power to make clinical decisions contrary to mutual previous agreements, as it was when the surgeon annulled nurses' AP. The performance of AP contrary to nurses' own professional values turned out to be consequences of co-worker's, not only surgeons', extreme unconcern of AP. It led to experiences of professional exhaustion arising from the helplessness as a nurse to provide good nursing care.

In this, as in any other qualitative study, all the aspects of social organisation were not described (Peräkylä 2004). For example, the effects of on-call work on the AP were not

discussed deeply during the interviews. All the operations took place during morning shifts, but it may be possible that the previous on-call shifts affected the performance of AP. The nurses' experiences of AP-related stress were at the focus of this study; the results and the cultural assumptions showed that in the future it would also be important to study the surgeons' points of views more closely. Surgeons and nurses share these experiences in the sterile field and more careful participation of surgeons in AP is both an ethical and patient safety issue. The findings of Flin *et al.* (2006) challenged the cultural assumptions of SNs by showing that surgeons are concerned about patient safety as the nurses are.

Much time was used to transcript, analyse and translate this challenging data. This may be considered as a bias or as an advantage when reporting as ethically and methodologically demanding an issue as AP. The potential correlations between AP and surgical infections are difficult to prove, and they are contaminated by several variables, like AP-related stress.

In the study surgery, the visible, hidden or relative factors for AP-related stress were defined via: time; equipment; person; patient; work experience; working-morals; power and physical stress. Our findings get support from international literature. In Sigurdsson's study (2001), the meaning of being a perioperative nurse was defined as arising out of three patterns: money, power and forces of colonisation. The regulation of space and time to maintain the integrity of the sterile field was earlier identified as a focus of clinical management in surgery (Riley & Manias 2002) and as a dominant catalyst for tension between surgeons' and nurses' in communication (Espin & Lingard 2001). In the study of Flin *et al.* (2006), surgery personnel were reported more likely to make more errors in tense or hostile situations. Owing to patient safety, it is important to improve the working atmosphere in surgeries.

The AP-related stress factors in this study were like the ones introduced in international literature: surgeons using power and 'personal' supplies (Timmons & Tanner 2005) and working-morals-related problems like the breaks in sterile technique (Killen 2002). In the study surgery, the presence of potential infectious diseases and hazards was a stress factor when working with a careless or fussy colleague. Nurses frequently referred to surgeons' bad tempers, shouting and tantrums (Silén-Lipponen *et al.* 1999, Timmons & Tanner 2005). They did not want to upset surgeons and used conversation in stress reduction. An interesting difference was found in the means of reducing the stress caused by instruments: SNs in the UK hide instruments for the surgeon (Timmons & Tanner 2005). Nurses in the study surgery hide instruments from the surgeon. The difference may be explained by levels of expertise and activity in work (Silén-Lipponen *et al.* 2002, Torjuul *et al.* 2007). In this study, the expert nurses used their expert power were cunning, but also turned a blind eye to the 'hopeless person'. Competent SNs did not want to disturb the surgeon's AP owing to 'the peace in the surgery'. Novice nurses felt that they were 'not in a position to give feedback to a surgeon or senior colleague'. In this study, most SNs, like the nurses in the study of Killen (2002), wanted to keep the surgeon happy and argued for it by advocating the best interests of the patients. Some were assertive when needed, as in the studies of Silén-Lipponen *et al.* (2002) and Flin *et al.* (2006), some withdrawn, as in the study of McGarvey *et al.* (2004).

Nurses' reactions to co-workers' actions were introduced by a scale with a wide range of emotional responses to stress. Both surgeons and nurses awoke strong emotions. In the study surgery, the hierarchy between and within professions was present in the working-morals- and power-related AP. As in international studies, some SNs reported it existing between surgeons and surgery nurses, and some between junior and senior nurses (Silén-Lipponen *et al.* 2002, McGarvey *et al.* 2004, and Flin *et al.* 2006). It was found to lead to negative skill discretion in AP performance. SNs did not always have freedom or authority to make judgments and to act as they saw fit. According to Nielsen *et al.* (2004), the lack of professional authority and support from superiors may lead to increased absence as a predicator of occupational stress.

A potentially increasing future stress factor was the lack of knowledge concerning the education and the clinical competencies of a foreign-educated nurse co-worker. The differences in clinical competencies, cultural sensitivity and working morals are the concerns about foreign-educated nurses (Stone *et al.* 2004). The ability to trust all the colleagues was found necessary in AP also by Björn and Lindberg Boström (2008), Silén-Lipponen *et al.* (2004) and Flin *et al.* (2006). That is why it is important that surgery personnel can talk to one another, support each other and agree with each other (Sørlie *et al.* 2005, Flin *et al.* 2006, Juthberg *et al.* 2007, and Torjuul *et al.* 2007).

The means to reduce AP-related stress were bipolar: the SNs balanced carefully between supplicant and rebel; between surgeon's perceptions and goals, and their own ones. The SNs were not necessarily obedient servants of surgeons. The choice of which means they used was often person and situation specific. Some nurses ensured professional survival in demanding situations or with demanding persons. They behaved like surgery nurses in the studies of McGarvey *et al.* (2004) and Björn and Lindberg Boström (2008) where the main concern of some nurses' was to be prepared for the operation. Timmons and Tanner (2005) defined the role of surgery nurses as that of a hostess and their means to reduce work-related stress as unprofessional. In this study, some nurses, like nurses in studies

of Silén-Lipponen *et al.* (1999), Chard (2000), Espin and Lingard (2001), Sigurdsson (2001), Riley and Manias (2002) and Bianchi (2008), practised ethically for the good of the patients. They expressed empathy, flexibility and caring in teamwork and ensured positive experiences for their patients. This constructive strategy may be useful when decreasing the stress of SNs. It may also increase the independence and improve the role definition of the SNs in the context of AP (McGarvey *et al.* 2000, Flin *et al.* 2006).

The results of this study showed that despite competent Finnish surgery nurses efforts to advance good AP, there still are challenges to reducing the obstacles to reach 'Scandinavian equality' and increase the professional courage to advocate the patients' best interests in the surgery team. Some SNs valued both the technical expertise and the courage to exhibit their professional expertise under pressure. The findings showed that the surgery nurses are in a position where it is possible to construct professional expertise in AP by hard clinical work, use of evidence-based knowledge and development of clinical means to advance AP as a professional skill. As Finnish philosopher, Ilkka Niiniluoto (1993, 1996) stated the technical norms bind only those who accept their value basis.

Conclusions

In this study, AP-related stress was found to be an important part of surgery work. It was present as negative and positive experiences related to both medical and nursing co-workers. SNs reduced their AP-related stress by turning a blind eye, giving feedback or expressing clinical expertise in AP. The means they used varied according to the level of SN's expertise and were co-worker and situation specific. That is why constructive means are recommended when solving conflicts and replacing person-related AP with evidence-based one. This would support professional growth, reduce stress and, by these, improve the surgical patient care.

Relevance to clinical practice

The results of this study supported the findings of Silén-Lipponen *et al.* (2002) and Flin *et al.* (2006) when pointing out the need to create evidence-based recommendations for AP in multiprofessional cooperation to secure the well-being of the all personnel in the surgeries. In the context of evaluative programmes, it is possible to increase the understanding of AP performed neither without harming the surgeon nor on the behalf of the nurses only, but of all patients, all personnel and the safe surgery environment. The findings support the need to decrease time-related stress in surgery to prevent the personnel from suffering chronic fatigue syndrome (Nicol & Botterill 2004, Kara *et al.* 2008). Also, it would be useful to study time-related stress more as a risk for patient safety (Flin *et al.* 2006).

The results of this study like the ones of Silén-Lipponen *et al.* (2002), Storch and Kenny (2007) and Flin *et al.* (2006) showed the need for joint education; supporting members of personnel in fulfilling their multiple commitments; recognition of the conflicts; planning actions to reduce conflicts and learning to work in collaboration. All these would be useful and cost-effective ways to decrease the stress and stress-related absence in surgery (Nielsen *et al.* 2004). Learning from errors and near misses as exemplars of system vulnerabilities might possibly provide direction for developing improvement strategies for clinical AP (Jeffs *et al.* 2008). It also may increase the interest in surgery nursing as a professional career in the future. A shared multiprofessional agreement and documentation of AP is needed to increase the adherence to AP recommendations. Sound practices and ongoing education may be useful when improving and solving nurses' occupational infections, and recruitment and retention problems (Silén-Lipponen *et al.* 2002, Stone *et al.* 2004, van den Tooren & de Jonge 2008).

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Contributions

Study design: T-KA; data collection and analysis: T-KA and manuscript preparation: T-KA.

Conflict of interest

There is no conflict of interests to declare.

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II

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POST SURGICAL CARE

Risk factors for surgical site infection in breast surgery

Aholaakko Teija-Kaisa, Metsälä Eija, Sihvonen Marja and Lyytikäinen Outi

Aims and objectives. To study risks of surgical site infection in breast surgery. The objectives were to measure the association of postoperative infection with patient- and procedure-related factors.

Background. The infection rate in breast surgery is expected to be low but it varies a lot. The variation is recommended to be assessed by measuring procedure-related factors.

Design. A retrospective chart review of 982 breast surgery patients was completed.

Methods. The data on patient demographics, procedure types, patient and surgery-related factors were collected. A multivariate logistic regression model for all breast operations (n = 982), lumpectomies (n = 700) and mastectomies (n = 282) was performed.

Results. The infection rate was 6·7%. In a multivariate logistic regression model for all operations, a contaminated or dirty wound, high American Society of Anesthesiologists score, high body mass index, use of surgical drains and re-operation predicted increased infection risk. In lumpectomies high body mass index and use of surgical drains predicted increased risk. In mastectomies, the significant predictor was re-operation.

Conclusions. The surgical site infection rate was high. In addition to the two classical risks (high wound class and anaesthesia risk), high body mass index, re-operation and use of surgical drain increased the infection risk among all patients.

Relevance to clinical practice. In breast surgery careful assessment, documentation and adherence to aseptic practices are important with all patients. Patients with heavy weight need special attention. The need for antimicrobial prophylaxis in re-operations and the need of surgical drains in lumpectomies are important to consider carefully.

Key words: breast surgery, lumpectomy, mastectomy, patient-related risk factors, procedure-related risk factors, surgical site infection

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Introduction

This study describes some results of a quality improvement programme aiming to improve aseptic practices (AP) in surgeries of one Finnish university hospital (Aholaakko 2011). During the programme, the Association of Operating Room Nurses (AORN 1999) recommendations were culturally validated and documented with evidence base. The AP was defined as means of minimising wound contamination during invasive procedures. The AP was classified by six subcategories: (1) preparation of the personnel; (2) preparation of the patient for the surgery; (3) central services; (4) environmental services; (5) aseptic behaviour and (6) aseptic technique during creation, maintenance and discharge of the sterile field. The breast surgery patients were defined as a target patient group, and the postoperative surgical site infection (SSI) rate was used as an outcome indicator of the programme. There was no statistically significant

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improvement in it after the programme. This study describes the patient-related and procedure-related risk factors for the SSI after breast surgery.

Background

Breast surgery is classified as 'clean' surgery in which the expectation of SSI is low [Centers for Disease Control & Prevention (CDC) 2004, Alexander *et al.* 2011, de Blacam *et al.* 2012]. The SSI rates after mastectomies varied from 1·7–11%, so that after a primary mastectomy, the rate was from 2·6–6·4% and after reoperation from 7·6–11% (Chen *et al.* 1991, Jarvis *et al.* 1998, Gaynes *et al.* 2001, Moro *et al.* 2005, Monge Jodrá *et al.* 2006, Rioux *et al.* 2007). Inadequate wound care was reported among breast cancer patients with a SSI rate of 13·7–33·1% (Vilar-Compte *et al.* 2006). The rate was 18·9% after a quality improvement programme (Vilar-Compte *et al.* 2009). In the research hospital of the current study, the adherence to the AP-recommendations during breast surgery was varying a lot and it was found as stressful (Aholaakko 2011).

Complications like SSI cause readmissions and subsequent surgeries with increased hospital costs and considerable patient distress (Olsen *et al.* 2008, de Blacam *et al.* 2012). Procedure-related factors are recommended to be measured if large variation exists in SSI rate between hospitals (Geubbels *et al.* 2006).

Risk factors in breast surgery and universal patient-related SSI risk factors (high wound class, high American Society of Anesthesiologists (ASA) score and long duration of operation) were found as controversial [National Nosocomial Infection Surveillance (NNIS) 2002, Miner *et al.* 2004, McKibben *et al.* 2005, Prospero *et al.* 2006, Bunn *et al.* 2006, Friedman *et al.* 2007, Rioux *et al.* 2007].

The SSI rate was reported as lower in non-cancer than in breast cancer surgery (Olsen *et al.* 2008, Vilar-Compte *et al.* 2009). This may be due to the high risks of more extensive procedures with drain usage (Throckmorton *et al.* 2009). Also the preoperative chemo and radiation therapy, haematoma, the body mass index (BMI) 30 kg/m^2 or over, age of 58 or over and long duration of surgery (160 minutes or more) were defined as SSI risks (Olsen *et al.* 2008, Vilar-Compte *et al.* 2009).

According to de Blacam *et al.* (2012), the mastectomy patients had more SSIs (3·2%) than lumpectomy patients (1·4%). They tended to have more co-morbidities, like diabetes mellitus (DM), and they were older than lumpectomy patients. The independent SSI risks of both mastectomy and lumpectomy patients were BMI of 25 kg/m^2 or higher and being a smoker. The independent SSI risk of lumpectomy patients was having a prior operation within 30 days. Among mastectomy patients, the mean age and the mean duration of the hospital stay were higher for those with infection than for those without infection (Chen *et al.* 1991, Vilar-Compte *et al.* 2006, Olsen *et al.* 2008.)

Prospective randomised studies have shown a clear benefit after the use of antimicrobial prophylaxis (AMP) in elective operations such as breast procedures (Alexander *et al.* 2011). In small scale or clinical studies, the benefit was not this clear. In breast surgery without AMP, a single antimicrobial dose administered approximately 30 minute before surgery; the SSI risk was reported as 12% (Platt *et al.* 1990). AMP of 24-hours duration compared with postmastectomy antimicrobials reduced SSI rate from 7·6–3·4% (Chen *et al.* 1991). AMP was recommended in mastectomy of patients with cancer, but a reduction in SSI rate was not always observed (Bunn *et al.* 2006). No statistically significant SSI reduction was found among patients who received both pre- and postoperative AMP compared with those with preoperative AMP only (Throckmorton *et al.* 2009). According to Wagman *et al.* (1990), the AMP administration 30 minute before skin incision did not reduce SSI rate, but prolonged SSI onset.

Perioperative interventions breaking the skin integrity were potential SSI risks. Surgical removal of hair was reported to be associated with SSI when the hair was removed by a razor (Alexander *et al.* 2011). Using the clippers resulted in fewer SSIs than using a razor (Kjønniksen *et al.* 2002, Tanner *et al.* 2006). In mastectomies, all postoperative SSIs were reported after axillary dissection, half of these in the open biopsy site (Wagman *et al.* 1990). Complications were not reported after wire-guided biopsies (Chadwick & Shorthouse 1997). Preoperative marking of tumours with wire or ink was not associated with SSI, but core needle biopsy with older age predicted a SSI risk of 15% (Witt *et al.* 2003).

The postoperative use of closed suction drains might be useful for the removal of fluid from large potential dead spaces, but did not prevent infections (Alexander *et al.* 2011). In general surgery (including mastectomies), the use of surgical drains for longer than five postoperative days increased SSI risk (Moro *et al.* 2005). The use of surgical drains increased pain and prolongs hospital stay after mastectomy and lumpectomy, but no difference in SSI rate was reported (Jain *et al.* 2004). After lumpectomy or mastectomy, SSI did not occur with the use of surgical drains unless the fluid volume was under 50 ml (Oertli *et al.* 1994). The pre- and postoperative administration of AMP did not reduce the SSI rate of patients with nine days

median length of time to drain removal when compared with those who received preoperative AMP only (Throckmorton *et al.* 2009).

In the present study, we focused on the risks of SSI in breast surgery. Our objectives were to measure whether the SSI after lumpectomy or mastectomy was associated with (1) patient-related factors and (2) procedure-related factors.

Methods

Data collection

Data regarding breast surgery ($n = 1042$) were collected from January 1999–November 2000 and from January 2002–March 2003 in two hospitals of Helsinki University Central Hospitals (HUCH). The documents of one patient were unavailable, and those from another patient were incomplete. Patient charts were delivered according to computer-based lists. All surgery-related documents were reviewed. Data were also searched from computer-based operation statistics. The type of surgery was identified using the name, national identity code, procedure codes and diagnosis of the patient. The registered SSIs that occurred within 30 days after the operation were diagnosed by a physician according to the classical symptoms of infection: purulent drainage; spontaneously dehisced incision; or wound opened by a surgeon, and classified as 'superficial', 'deep incisional' or 'organ space' (Emori *et al.* 1991, Crowe & Cooke 1998, Wilson *et al.* 2004). The Infection Control Nurses of study hospitals validated the registered SSIs from hospital infection registers and confirmed the unregistered SSIs from patient charts and data collection forms together with one of the researchers (T-KA) at the end of data collection.

The following data of patient-related risk factors were collected: age ≥ 65 years; ASA score of 3–5; presence of DM; presence of re-operation; and a BMI of ≥ 25 kg/m^2, calculated as height in kilograms divided by height in metres squared (de Blacam *et al.* 2012). Preoperative hospital stay of 48 hours or more; administration of AMP defined as a single antimicrobial dose administered 30–60 minute before surgery (Platt *et al.* 1990); surgical removal of hair; skin condition; invasive tumour marking; and use of surgical drains were used as procedure-related risk factors. The risk due to the long-operating time was identified in the fourth time quartile of observed operations instead of the National Nosocomial Infection Surveillance (NNIS) cut-off point of two or three hours (Jarvis *et al.* 1998).

Statistical analysis

Descriptive characteristics of the patients with breast cancer and operations were measured. The patient- and procedure-related characteristics were used as independent variables when calculating the initial risk factors for SSI. All breast-operated; lumpectomy; and mastectomy patients with SSIs were compared with those without SSIs. Univariate odds ratios (ORs) were calculated first (Table 1). The dependent variable (SSI) was dichotomised. It was coded simply 0 = no SSI, 1 = defined SSI. This caused loss of information, but made it possible to use logistic regression as an analysis method. Using logistic regression instead of general logistic modelling gave a more reliable prediction because the dependent variable did not distribute according to a normal curve. Variables of patient- and procedure-related factors were used as covariates. Dichotomous variables were formed out of some independent variables as the candidate risk factors for SSI. For the multivariate models, they were selected on the basis of previous research and significance of univariate analysis. The methodological grounds for this were to improve the reliability of clinical data (Munro 1997, 287–309, Gomm 2004, 139–149).

Separate multivariate logistic regression models for all observed operations, and for lumpectomies and mastectomies, were carried out. The intervals (CI) were reported to demonstrate more clearly the odds ratio and the statistical significance of the results. For the logistic regression, the normality of residuals was tested by probability plots. The homoscedasticy of residuals was explored by plotting residuals. Residuals appeared to be randomly scattered. The −2 Log Likelihood (−2LL) was used as a measure of how well the estimated model fits the data. A good model is one that results in a high likelihood of the observed results. (Munro 1997, 287–309.) Statistical analysis was performed with the SPSS software package version 16.0 (SPSS Inc., Chicago, IL, USA).

Results

The study consisted of 982 breast operations. The age range of breast surgery patients was 16–97 years, with a mean of 55 (±12·57) years. Ninety-eight per cent of patients were women. Six per cent of patients had signs of preoperative infection. The cancer was diagnosed preoperatively in 61% of subjects. DM rate was four per cent. BMI of the patients varied from 11–55 kg/m^2.

Eighty-four per cent of patients arrived at the hospital on the day of surgery and one per cent earlier. Fifteen per cent visited the hospital day before surgery. Surgical hair removal was documented to perform in 41% of the

Table 1 Demographic and clinical characteristics of breast surgery patients

	Surgical site infection rate				
	Yes *n* (%)	No *n* (%)	Univariate OR	*p*	CI 95%
Patient-related factors					
Age (years)					
≤65	49 (6·2)	739 (93·8)	1·57	0·118	0·89–2·76
>65	18 (9·4)	173 (90·6)			
Total	67 (6·8)	912 (93·2)			
American Society of Anesthesiologists (ASA) score					
1 or 2	47 (5·7)	774 (94·3)	2·44	0·002	1·40–4·24
3–5	20 (12·9)	135 (87·1)			
Total	67 (6·9)	909 (93·1)			
Wound class					
1 or 2	62 (6·4)	905 (93·6)	8·34	0·001	2·38–29·26
3 or 4	4 (36·4)	7 (63·6)			
Total	66 (6·7)	912 (93·3)			
Diabetes mellitus					
No	64 (6·8)	878 (93·2)	1·18	00·792	0·352–3·928
Yes	3 (7·9)	35 (92·1)			
Total	67 (6·8)	913 (93·2)			
Body mass index (kg/m^2)					
<25	20 (4·6)	418 (95·4)	2·13	0·007	1·22–3·71
≥25	40 (9·3)	392 (90·7)			
Total	60 (6·9)	810 (93·1)			
Re-operated patient					
No	37 (5·2)	673 (94·8)	2·25	0·002	1·36–3·73
Yes	30 (11)	242 (89·0)			
Total	67 (6·8)	915 (93·2)			
Procedure-related factors					
Preoperative hospital stay (hour)					
<48	67 (6·9)	907 (93·1)	–	–	–
≥48	0 (0·0)	5 (0·5)			
Total	67 (6·8)	912 (93·2)			
Timing of preoperative antimicrobial prophylaxis (AMP)					
30–60 minute before incision	4 (17·4)	19 (82·6)	0·334	0·053	0·110–0·013
No AMP or inadequate timing of AMP	63 (6·6)	895 (93·4)			
Total	67 (6·8)	914 (93·2)			
Preoperative surgical removal of hair					
No	42 (7·3)	536 (92·7)	0·85	0·523	0·51–1·41
Yes	25 (6·2)	377 (93·8)			
Total	67 (6·8)	913 (93·2)			
Preoperative skin condition					
Intact	18 (9·0)	181 (91·0)	1·48	0·172	0·84–2·65
Non-intact	49 (6·3)	730 (93·7)			
Total	67 (6·9)	911 (93·1)			
Invasive preoperative tumour marking					
No	45 (6·9)	605 (93·1)	0·96	0·890	0·57–1·63
Yes	22 (6·7)	307 (93·3)			
Total	67 (6·8)	912 (93·2)			
Axillary evacuation					
No	22 (5·2)	397 (94·8)	1·57	0·093	0·93–2·66
Yes	45 (8)	517 (92)			
Total	67 (6·8)	914 (93·2)			

Table 1 (Continued)

	Surgical site infection rate				
	Yes *n* (%)	No *n* (%)	Univariate OR	*p*	CI 95%
Surgical drain					
No	10 (3)	325 (97)	3·14	0·001	1·58–6·23
Yes	57 (8·8)	590 (91·2)			
Total	67 (6·8)	915 (93·2)			
Duration of surgery (minute)					
<87	45 (6·2)	680 (93·8)	1·50	0·137	0·88–2·55
≥87	22 (9)	222 (91)			
Total	67 (6·9)	902 (93·1)			

operations. Preoperatively the patients' skin in surgical site was assessed as intact for 80% of the operations. Signs of preoperative infection were noted in six per cent. Preoperative invasive procedures were performed in 55% of operations. Sentinel puncture was made in 10% of operations, wire marking in 35% and other punctures (e.g. ink application) in three per cent of operations. Rest of the patients had anaesthesia-related punctures.

Antimicrobials were administered in seven per cent of the operations ($n = 69$). In fifteen operations AMP was administered 30 minutes prior incision and in eight operations closer than that. In six operations, it was given during incision and in 25 operations after it. In fourteen operations, the time of administration was not documented. AMP was administrated for a reason other than surgery to one patient. The surgeon had influenza.

Of 982 breast operations 700 (72%) were lumpectomies and 282 (28%) mastectomies with or without axillary dissection. Fifty-seven per cent of all patients had an axillary evacuation. The occurrence of re-operations was 28% and that of several re-operations one per cent. Mean operation time was 64·83 (±40·38) minutes. Operating time comprised a first quartile of 3–32 minute, second of 33–58 minute, third of 59–86 minute and the fourth quartile of 87–502 minute. The 75th percentile cut-off time was 87 minutes.

Sixty-six SSIs were identified. The SSI rate among all breast operations was 6·7%; after lumpectomy 4·7%; and after mastectomy 8·9%. The most common SSIs were deep incisional ($n = 37$, 56%), followed by superficial ($n = 22$, 33%) and organ space ($n = 7$, 11%). In 24% of 769 documents, it was possible to define variation of postoperative visits to hospital. Of the patients 111 had more than one postoperative visit. Eighty-seven patients visited in surgical ward and 19 (1·9%) in Emergency Room because of to SSI. One patient had a health centre visit. Eleven patients (1·1%) had readmission because of to SSI and four (0·4%) because of systemic complications.

Patient- and procedure-related initial risk factors for SSI were identified (Table 1). The risk was increased for patients with ASA scores of 3–5 compared with patients with ASA score 1 or 2. If the wound class was 'contaminated' or 'dirty', the risk of SSI was higher than for 'clean' or 'clean contaminated' wounds. Three patients were classified as having a contaminated wound, and six as having a dirty wound. The BMI of ≥ 25 kg/m^2 increased the SSI risk. Re-operated patients had higher SSI risk compared with patients who had one operation.

The multivariate logistic regression models were calculated for all operations, lumpectomies and mastectomies to predict SSI risks (Table 2). In all operations, four patient-related risks were found to be statistically significant. Patients with an ASA score 3–5 had a higher SSI risk compared with healthy patients. Contaminated or dirty wound class predicted an increased SSI risk. Patients with a BMI $\geq$ 25 kg/m^2 had a higher risk of SSI compared with patients having normal or low weight. The risk of re-operated patients was higher when compared with patients who had undergone one operation. Re-operation predicted increased patient-related SSI risk both in lumpectomies and mastectomies. A high BMI increased SSI risk in lumpectomies.

One procedure-related factor was statistically significant. Use of a surgical drain predicted increased risk of SSI in all operations. The risk was statistically significant also in lumpectomies, but not in mastectomies (Table 2).

Discussion

In this study, the SSI rate was high when compared with the international recommendations (Olsen *et al.* 2008, Alexander *et al.* 2011). After lumpectomy, the rate was 4·7% and 8·9% after mastectomy. This kind of difference

Table 2 Surgical-site infections among all breast-operated, lumpectomy and mastectomy patients by patient- and procedure-related factors

Surgical site infection rate (%)	All breast-operated patients (n = 982)			Lumpectomy patients (n = 700)			Mastectomy patients (n = 282)		
	66 (6·7)			33 (4·7)			25 (8·9)		
	OR	p	CI 95%	OR	p	CI 95%	OR	p	CI 95%
Patient-related factors									
ASA score 3–5	2·1	0·018	1·13–3·90	2·0	0·110	0·54–4·72	1·9	0·147	0·79–4·95
Contaminated or dirty wound	6·8	0·014	1·47–31·27	4·2	0·217	0·43–1·74	11·9	0·051	0·99–44·93
BMI $\geq$ 25 kg/m^2	1·8	0·038	1·03–3·33	2·6	0·028	1·11–6·03	1·4	0·454	0·59–3·29
Re-operated patient	2·6	0·001	1·53–4·61	2·4	0·017	1·17–5·04	2·7	0·027	1·12–6·39
Procedure-related factors									
Surgical drain	3·3	0·003	1·52–7·11	3·2	0·008	1·35–7·62	1·3	0·857	0·14–10·34
Multivariate model summary	−2LL = 388·670			−2LL = 230·135			−2LL = 155·563		
Missing cases	118			88			30		

ASA, American Society of Anesthesiologists; BMI, body mass index; −2LL, 2 log likelihood.

was reported earlier (Throckmorton *et al.* 2009), and it was used to justify the procedure-specific follow-up of SSI in this study. The SSI rates in the present study were higher than in most surveillance studies [Jarvis *et al.* 1998, Yokoe *et al.* 1998, National Nosocomial Infection Surveillance (NNIS) 2002, Monge Jodrá *et al.* 2006], but lower than in the observational studies of Vilar-Compte *et al.* (2006, 2009). The variations in SSI rates may occur because of the differences in data collection. According to Moro *et al.* (2005), the intensity of postdischarge surveillance may in part explain the observed difference in SSI rate.

The classical patient-related risks of SSI (Emori *et al.* 1991) were supported by the results of univariate analysis. In multivariate analysis, the presence of high ASA score; contaminated or dirty wound; and high BMI were the patient-related risk factors in all operations. In lumpectomy (but not in mastectomy), a high BMI was the most predictive patient-related risk. This may be due to the procedure; the small number of mastectomies in the present study; or the used BMI value which was lower than the one used by Vilar-Compte *et al.* (2006, 2009) and Olsen *et al.* (2008). In future studies, in addition to classical SSI risks, it would be important to control the skin condition at the surgical site, as well as the performance of the axillary component of the surgery. This might help to separate patient- and procedure-related risks and enhance the prediction of SSI risk (Reilly *et al.* 2006).

The importance of procedure-related factors for SSI has been discussed, but consensus concerning the indicators is lacking. In the present study, AMP was administrated to only seven per cent of the patients, which may be too low to improve the SSI rates. In the literature, the association between AMP and SSI is controversial (Miner *et al.* 2004, Geubbels *et al.* 2006, Monge Jodrá *et al.* 2006). Our findings support the recommendation to consider preoperative AMP for the patients with breast cancer, especially for those having re-operations (Bunn *et al.* 2006). Re-operation increased the SSI risk in all breast surgery. It was the only statistically significant patient-related risk factor in mastectomies. The high number of readmissions and subsequent surgeries because of SSIs cause increased hospital costs and stress for the patients. High infection rate of mastectomy patients is important to decrease as a result of the success of the potential postmastectomy breast-reconstructions. (Olsen *et al.* 2008, Throckmorton *et al.* 2009).

Of the procedure-related factors, surgical removal of hair, invasive interventions and breaks in skin integrity did not predict the SSI. In this present study, surgery nurses documented a high number of problems related to skin integrity, but defined few wounds to be contaminated or dirty. This may represent the real preoperative situation or underestimation of the contaminated or dirty wounds. In future studies, it would be beneficial to document the wound class of the operation according to the current situation, not the type of surgery. This is important when investigating the association between SSI and preoperative interventions with controlled skin integrity. It will be important also when measuring the association between SSI, AMP and the number of re-operations more carefully than in this study.

The NNIS-derived operation time for mastectomy has increased since the 1990s [National Nosocomial Infection Surveillance (NNIS) 2002, Miner *et al.* 2004]. It is criticised as being too long (Friedman *et al.* 2007). The locally calculated procedure-specific operating time cut point over 75th percentile is advised to used instead (Moro *et al.*

2005, Prospero *et al.* 2006, Vilar-Compte *et al.* 2006). In this study, the operation time, first measured as a continuous, later as a dichotomous variable, was not a statistically significant risk of SSI. The local cut-off time of the 75th percentile (87 minutes) instead of the two to three hours operation time recommended by the NNIS [Jarvis *et al.* 1998, National Nosocomial Infection Surveillance (NNIS) 2002, Friedman *et al.* 2007] was used. Compared with the operation times of this study, the NNIS time occurred to be too long. So the results of this current study should be compared with the results of NNIS with care.

Geubbels *et al.* (2006) pointed out that procedure-related SSI risk factors should measure common practices, be valid for various healthcare settings and be clearly specified. Factors like the use of surgical drains vary according to surgery type. The use of drains is associated with pain and increased hospital stay, but not necessarily with increased rate of SSI (Jain *et al.* 2004, Classe *et al.* 2006). The exposure to open surgical drains for over five days increased the risk of SSI (Moro *et al.* 2005). In the present study, there was an association between the use of closed surgical drains and increased SSI rate in all operations and lumpectomies, but not in mastectomies. This may be due to the difference in size of the study groups. It also may indicate a tangible difference between the groups. In the future, it is important to test these findings in more carefully constructed study groups. The importance of relevant surgical and aseptic techniques with surgical drains during intra- and postoperative care is important to study. Existence of postoperative seroma, type of vacuum used, amount of fluid drained, maintenance of a closed system and the time of drain removal might be interesting parameters to investigate.

Study limitations

In this study, the data from patient documents and hospital statistics were used. It was collected as a routine part of care and reflected the conditions, treatments and definitions made in clinical settings by many surgical professionals (Gastmeier *et al.* 1999). This possible lack of consistency and under-reporting may cause unreliable judgements (Gomm 2004, 139–149). The missing data excluded 22 patients from the SSI risk analysis. The aim was to collect simple and objective data, but the comparability of the results of present study and those in the literature is limited [Gaynes *et al.* 2001, National Nosocomial Infection Surveillance (NNIS) 2002, Bunn *et al.* 2006, Monge Jodrá *et al.* 2006, Prospero *et al.* 2006]. The broad confidence intervals of some variables (Table 1) meant that the study group was not large and homogenous enough.

Making the dependent variable (SSI) dichotomous caused loss of information, but made it possible to use logistic regression as an analysis method. Using logistic regression instead of general logistic modelling gave a more reliable prediction because the dependent variable did not distribute according to a normal curve. We formed dichotomous variables out of some independent variables. The methodological grounds for this were to improve the reliability of clinical data (Munro 1997, 287–309, Gomm 2004, 139–149).

Ethical considerations

The appropriate hospital authorities gave permission to conduct this study in surgeries of two HUCH hospitals. After the target patient group was identified, the ethical board of HUCH gave their acceptance. Good ethical practice, privacy and respect of the rights of patients and personnel were undertaken during the study.

Conclusions

The overall SSI rate of observed breast operations was high when compared with international findings. The high ASA score, wound contamination and re-operation predicted the SSI of all breast-operated patients; and the use of drain and high BMI the SSI of lumpectomy patients. Re-operation was the only significant risk factor among all three study groups. It is therefore important to consider AMP for all re-operated breast surgery patients.

The use of surgical drains was identified as a procedure-related SSI risk in all breast operations and lumpectomies, but not in mastectomies. So the use of surgical drains and the other indicators used as procedure-related factors to predict SSI among breast-operated patients requires further investigation.

Relevance to clinical practice

According to Alexander *et al.* (2011), the target SSI rate in breast surgery is 0·5%. So the proper implementation of infection prevention guidelines to control the unacceptably high SSI rates is necessary. The findings of this study indicated the importance of more precise definition of the patient- and procedure-related risk factors for SSI in breast surgery. This study revealed also the need for more careful perioperative documentation of clinical aseptic practice and patient status information. In breast surgery careful patient assessment, detailed documentation and adherence to AP are important with all patients. Patients with heavy body weight need special attention. The need for AMP in

re-operations, and the management of surgical drains in lumpectomies are important to consider carefully.

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Contributions

Study design: AT-K, SM, LO; data collection and analysis: AT-K, ME and manuscript preparation: AT-K, ME, SM, LO.

Conflict of interest

There is no conflict of interests to declare.

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III

Intraoperative aseptic practice recommendations for circulating operating theatre nurses

Teija-Kaisa Aholaakko and Eija Metsälä

Abstract

Aseptic practices prevent exposure of a surgical wound to microbes, operating theatre environment and personnel. The circulating nurse assists the operating theatre personnel and supervises aseptic practices preventing surgical site infections. In the absence of analytical tools, few studies exist on intraoperative nursing-related aseptic practices. This study introduces recommendations to assess the role of the circulating nurse in aseptic practices. The authors used international recommendations and research findings to construct a 20-item self-report instrument with a demonstrated reliability across the scale. The authors structured the scale based on three phases: establishment; maintenance; and disestablishment of a sterile operating field. The tool was tested among operating theatre and day surgery nurses, and compared the differences in the mean acceptance rates of aseptic practice recommendations based on background characteristics. College-level nurses and nurses with 15 or more years' work experience accepted the recommendations at higher levels than bachelor-level nurses and nurses with less work experience. Continual assessment of the evidence base and comprehensive evaluation represent important components in further developing the tool. A reasonable number of items covering clinical practice are necessary for assessing the effectiveness and cost-effectiveness of aseptic practices, and a larger response rate is needed to validate the tool in future.

Key words: Infection control ■ Infection prevention ■ Antisepsis ■ Asepsis ■ Aseptic technique ■ Surgery ■ Operating theatre

In the EU approximately 4 million patients acquire healthcare–associated infections each year. The most frequent infections include urinary tract infections, respiratory infections, postoperative infections and blood stream infections. Approximately 20–30% of these may be prevented through intensive hygiene and infection control programmes. Effective infection prevention is defined as one of the key components of safe patient care globally (EU Council, 2009; World Health Organization (WHO), 2011; Association for Professionals in Infection Control and Epidemiology (APIC), 2012; European Centre for Disease Prevention and Control (ECDC), 2015).

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The EU Council (2009) has encouraged the development of a specific approach to promote safe practices, ensure the development of skills and make guidelines and recommendations available at national and regional levels. These represent globally applied standards and recommendations for operating theatre teams to achieve the optimal level of technical and aseptic practices (Association of peri-Operative Registered Nurses (AORN), 2013). However, no direct evidence exists that these recommendations (except those for hand hygiene) reduce surgical site infections in patients (Rathnayake, 2014). Developing the content and conceptual structure of these recommendations represent important steps to ensure that they better address all phases of surgical procedures. Once developed, critically assessing and increasing the evidence base, and measuring the effectiveness and cost-effectiveness of aseptic practices, becomes possible.

This study aimed to develop the assessment of intraoperative aseptic practices, with the objective of studying intraoperative aseptic practices performed by circulating nurses. The research questions included:

- Which of the aseptic practice recommendations did nurses accept for circulating nurses during the establishment, maintenance, and disestablishment of the sterile field?
- Did the Aseptic Practices among Circulating Nurses scale reliably measure acceptance of the roles of circulating nurses in the aseptic practice recommendations?
- Were any differences detected in nurses' acceptance of aseptic practice recommendations between hospitals, working environments, education levels, work experience in a surgical unit in general, and work experience in the current position?

Background

Since 1995 international recommendations for aseptic practices have been applied and locally validated in the surgical departments of a university hospital in Finland (Aholaakko, 2011; Aholaakko et al, 2013). Similar to findings by Fung-Kee-Fung et al (2009), challenges in their application include: establishing trust among health professionals and health institutions; collecting accurate, complete and relevant data; clinical leadership; securing institutional commitments; and establishing infrastructure and methodological support for quality management.

The results of this intervention showed no improvements,

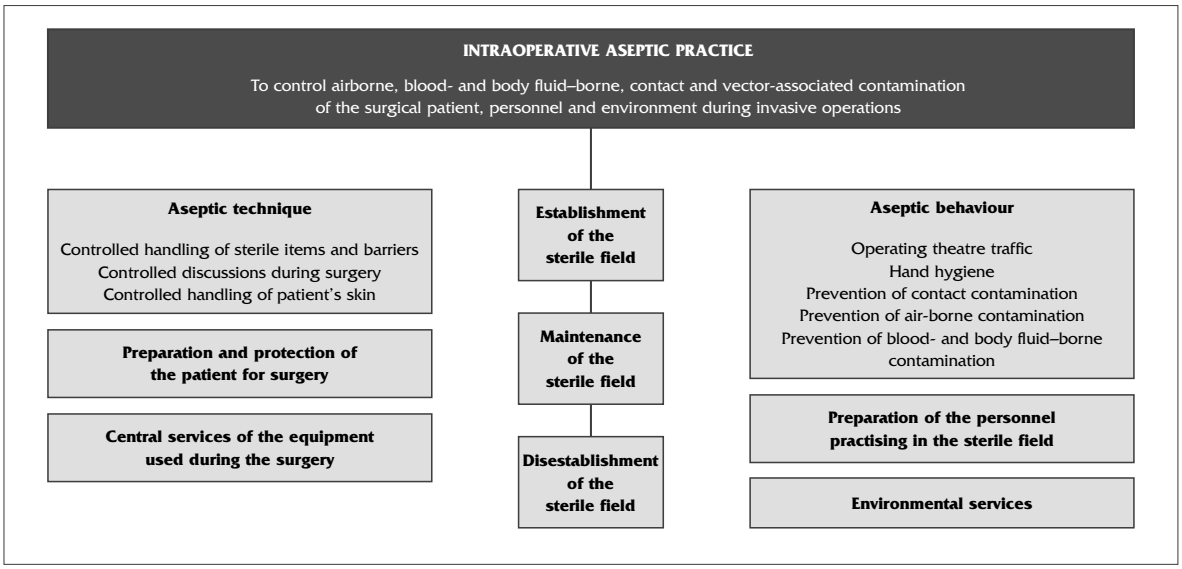

Figure 1. Model for intraoperative aseptic practices constructed for quality development in the operating theatre

but others found an increase in surgical site infection rates after breast surgery (Aholaakko et al, 2013). Tame (2013) reported negative results including no behavioural changes, but finding increased confidence and assertiveness after continuous perioperative education. In a study by Sinkowitz-Cochran et al (2012), nursing staff became better engaged and possessed greater knowledge of infection prevention than other healthcare workers. In another study by Sessa et al (2011), infection prevention knowledge was significantly higher among nurses with a higher level of education.

Studies on surgical practices demonstrate that awareness of role-related social order represents an important aspect of operating theatre culture, at times hampering the implementation of recommendations (Nestel and Kidd, 2006; Aholaakko, 2011; Tame, 2013). Disregarded recommendations (Adams et al, 2011; Aholaakko, 2011), individual knowledge (Gillespie et al, 2008; Tame, 2012), and skill-based intraoperative incidents (Angelillo et al, 1999) or errors (Flin et al, 2006; Jeffs et al, 2008; Smith, 2010) persist.

Previous studies (McGarvey et al, 2004; Timmons and Tanner, 2005; Gillespie et al, 2008; Richardson-Tench, 2008; Sinkowitz-Cochran et al, 2012; Yang et al, 2012) have shown that the role and influence of nurses are essential to operating theatre practices. In one study, the adherence of operating theatre personnel to aseptic practice recommendations varied and circulating nurses found such variation stressful (Aholaakko, 2011). The development of well-structured recommendations with a sound evidence base may improve not only infection status among surgical patients, but also the wellbeing of operating theatre team members.

Methodology

Aseptic Practices among Circulating Nurses scale

The authors developed the Aseptic Practices among Circulating Nurses scale, a self-report instrument, following the three phases of the operation: establishment of the sterile field before operation; maintenance of the sterile field during the operation; and disestablishment of the sterile field after the surgical wound is closed. The disestablishment of the sterile field does not mean that the sterile field is contaminated. *Figure 1* shows aseptic practice as a concept, serving a structure for the aseptic technique recommendations and a context for the perioperative aseptic practices.

The authors then completed a cross-sectional descriptive study to measure the acceptance of aseptic practice recommendations in 2013. Using a four-point scale (1 represented strong disagreement while 4 represented strong agreement) they constructed positive and negative multi-item statements rather than single-item rankings to avoid distorted results and improve reliability. Items were coded using a four-point score so that higher numbers represented stronger agreement with the recommendations.

The authors created the data collection instrument in early 2000. In an initial study, a hard-copy questionnaire was piloted among 22 operating theatre personnel unaffiliated with the study group in the project hospital district in 2000. In total, 17 nurses and physicians responded, assessing statements as easy to answer and the statements content as valid. Based on their feedback, the authors improved and clarified the wording of some statements. The revised instrument was used among registered operating theatre personnel from two hospitals in 2000 and 2001. In 2001, 106 of 234 (45%) questionnaires were returned.

In 2013, the authors updated the initial assessment tool and created an online questionnaire using some statements from the initial survey based on previous recommendations (AORN, 1999). In addition, the authors formulated questions according to AORN recommendations (2013). The instrument used in the present study comprised 20 statements. Owing to variations in

the evidence base and the structure of the conceptual model, a separate tool for measuring hand hygiene will be created.

Ethical approval

The ethics board of the university hospital district and the heads of medicine and nursing departments approved and accepted this study. Nurses were informed of the study during staff meetings and via email as part of the questionnaire. Returning the questionnaire was considered to be informed consent for the study.

Data collection

Online surveys were distributed to nurses from the operating theatre units of two university hospitals between October and November 2013. From a total of 242 nurses, 73 (30%) responded. From Hospital 1, 16 (27%) operating theatre nurses and 10 (21%) day surgery nurses responded after receiving two online reminders and a reminder from nursing managers. From Hospital 2, response rates reached 33 of 95 (35%) and 12 of 40 (30%), respectively. Two respondents did not identify their place of work and their questionnaires were not completed. Missing values were not replaced and owing to the low response rate, valid responses were analysed as a single study group.

Among all respondents, 45% held a bachelor-level nursing degree, while 55% were senior nurses who had received a college-level degree in nursing. All but three undergraduate bachelor-level nurses were registered. These three represented graduating students awaiting official registration upon completion of their practical placements. Among all respondents, 45% had worked in operating theatre units in general for 15 years or more. In terms of their current positions, 40% of respondents had worked in their current unit for less than 5 years, while 21% had worked in their current units for more than 15 years.

Data analysis

In total, the authors used 20 recommendations (none for hand hygiene) to describe aseptic practices from the circulating nurses' points of view. First, the authors completed descriptive statistics to introduce the acceptability of recommendations. Second, they counted summation variables according to the phases of specific operations. The aim was to construct a clinically relevant and reliable scale with three sub-scales: establishment of a sterile field; maintenance of a sterile field; and disestablishment of a sterile field. The authors chose meaningful constructions with possibly high alpha (a) values. The scale was tested by analysing the acceptance of recommendations according to the respondents' background characteristics. The Mann-Whitney U-test was used to explore the differences between ranked mean values for skewed data. For all analyses, results yielding $p<0.05$ were considered statistically significant.

Results

The authors constructed the Aseptic Practice among Circulating Nurses scale with an overall reliability of a=0.782. *Table 1* and the sub-scale reliability analyses show the acceptability of the recommendations and the characteristics of the summated variables. As a final step, the authors introduced the differences in acceptance based on background characteristics.

Aseptic practices for establishing a sterile field

The authors coded a 10-item (10/20) summated variable for the 'Establishment of a Sterile Field' sub-scale. Better reliability was found (a=0.605; mean=3.77; SD=0.232; minimum=3.00; maximum=4.00) than a previous study from 2001 using a five-item scale (a=0.564). All but one of the recommendations were rated as highly acceptable with a mean value of 3.61, with six recommendations receiving a mean value of 3.86 or higher. One of the recommendations focused on the selection of sterile items, while nine recommendations focused on aseptic technique when establishing a sterile field. Acceptance of the recommendation 'Create the sterile field less than an hour before the operation' received a lower acceptability than other recommendations (mean=3.23). Removing this item would increase the reliability of the scale overall; however, given its relevancy in clinical practice, the authors did not remove it from the analysis.

When testing the scale, statistically significant differences were found in the acceptance of recommendations according to the respondents' education, general work experience and time spent working in the current operating theatre. Senior nurses with college-level education (n=38) accepted the recommendations to a higher degree (mean=3.84; SD=0.201) than nurses with a bachelor's degree (n=30, mean=3.69; SD=0.309), a statistically significant difference (p=0.045). Acceptance was significantly higher (p=0.023) among nurses with 15 or more years' work experience in a general surgical unit (n=32; mean=3.84; SD=0.242) than among nurses with less work experience (n=36; mean=3.72; SD=0.270). There was a significantly higher (p=0.011) acceptance of recommendations among nurses with 5 years or more spent in their current position (n=42; mean=3.84; SD=0.227) than among nurses with less than 5 years' work experience in their current surgical unit (n=26; mean=3.68; SD=0.289).

Aseptic practices for maintaining a sterile field

The authors constructed a sub-scale for the 'Maintenance of a Sterile Field' using a summated variable for seven (7/20) recommendations. The authors found a moderate reliability for the sub-scale (a=0.639; mean=3.58; SD=0.362; minimum=2.29; maximum=4.00). The reliability was higher than the reliability of an eight-item scale from 2001 (a=0.620). There was high acceptance for recommendations on constantly supervising the sterile field, keeping doors closed and limiting the number of people in the operating theatre. There was less acceptance for the recommendation on limiting conversations during surgery. Only differences in the acceptance of recommendations between nurses with 15 or more years' work experience in the current operating theatre (n=14; mean=3.76; SD=0.272) and nurses who had worked for a shorter time in the current operating theatre (n=52; mean=3.53; SD=0.370) were statistically significant (p=0.018).

Table 1. The Aseptic Practices among Circulating Nurses scale			
Aseptic Practices among Circulating Nurses scale	**Mean (SD)***	**Cronbach's *α* reliability coefficient**	***α* if item deleted**
	3.44	0.782	
Establishment of a Sterile Field sub-scale	**3.77**	**0.605**	
Sterile indicators inspected before use†	3.95 (0.278)		0.532
Indicator gloves taken for high-risk operations†	3.95 (0.213)		0.519
Not using a sterile item after expiration date	3.94 (0.244)		0.536
Integrity of package inspected	3.89 (0.403)		0.541
Fluid transparency inspected before use†	3.89 (0.362)		0.435
Not using a damp sterile package*	3.86 (0.467)		0.513
Not using an opened sterile package*	3.73 (0.623)		0.551
Fluids and medicines decanted near use†	3.67 (0.714)		0.371
Filter needle used with liquids†	3.61 (0.748)		0.550
Sterile field created less than an hour before operation†	3.23 (1.046)		0.663
Maintenance of Sterile Field sub-scale	**3.58**	**0.639**	
Sterile field constantly supervised†	3.85 (0.404)		0.589
Doors kept closed during operation	3.80 (0.403)		0.622
Number of persons in operating theatre limited during operation	3.75 (0.501)		0.600
Defects in aseptic practices documented	3.71 (0.744)		0.623
Unscrubbed person not moving between two sterile fields	3.66 (0.594)		0.572
Circulating nurse stayed in operating theatre during operation†	3.26 (0.776)		0.638
Intraoperative conversation is aseptically important*	3.00 (0.901)		0.564
Disestablishment of Sterile Field sub-scale	**3.90**	**0.617**	
Gloves used during disestablishment of the sterile field†	3.97 (0.173)		0.388
Bloody gloves not removed outside operating theatre*†	3.91 (0.290)		0.578
Not disestablishing sterile field during wound closure*†	3.83 (0.414)		0.659

*Items reverted into 4-point scoring so that higher numbers represent stronger agreement with the recommendations
†Appears in the 2013 updated recommendations

Aseptic practices for disestablishing sterile field

The authors constructed a sub-scale for the 'Disestablishment of the Sterile Field' using three (3/20) recommendations. There was a moderate reliability for the scale (α=0.617; mean=3.90; SD=0.232; minimum=2.67; maximum=4.00). In 2001, only one recommendation focused on the disestablishment of the sterile field. In this study, a high level of acceptance for all three recommendations was found, with mean values of more than 3.8. These recommendations focused on the prevention of blood-borne infections and protecting the wound until it closes. Removing the item 'No disestablishment of the sterile field during wound closure' (mean=3.83) would increase the overall reliability of the scale; however, this item was not removed from the analysis given its clinical relevance.

In the analysis, there was a significantly higher (p=0.017) acceptance of the scale recommendations among senior nurses with a college-level education (n=37; mean=3.96; SD=0.105) than among nurses with a bachelor's degree (n=29; mean=3.83; SD=0.317). Nurses with 15 or more years' general operating department work experience (n=30; mean=3.97; SD=0.108) accepted the recommendations at a higher rate than nurses with less work experience (n=36; mean=3.85; SD=0.292), a statistically significant difference (p=0.039).

Discussion

This study aimed to assess the role of circulating nurses in intraoperative aseptic practices. Local recommendations were updated according to international recommendations (AORN, 2013), and studied among day surgery and operating theatre nurses. A previous qualitative study in one of the two operating theatres (Aholaakko, 2011) highlighted the necessity of developing the tool given the stress associated with performing aseptic practices. Another study aimed to identify the risk factors for surgical site infections (Aholaakko et al, 2013) through a review of records from more than 1000 breast surgery patients. Virtually no evaluative documentation of nursing-related aseptic practices was found. Given this, it was necessary to begin constructing tools for the assessment of intraoperative aseptic practices. In the costly work of operating theatre teams, relevant, reliable and valid tools to perform and assess clinical performance are essential.

This article introduces a tool that may serve as the starting point in developing performance, assessment, effectiveness and cost-effectiveness measurement of aseptic practices within a sterile operating field to protect the surgical patient, personnel and environment. Through this tool, it may be possible to enhance constructive communication and increase the

engagement of circulating nurses and the entire operating theatre team facilitating multidisciplinary improvements in aseptic practices (Nestel and Kidd, 2006; Gillespie et al, 2008; Aholaakko, 2011; Sinkowitz-Cochran et al, 2012; Tame, 2013).

Reliability of the scale

Precise and comprehensive scales accepted by health professionals are essential in measuring the performance and assessment of intraoperative aseptic practices. During the development of the assessment criteria, discussions must address the influence of statistical tools used to complete the focus of the evaluation. In the assessment of aseptic practice recommendations, this equates with aiming to reach only high reliability values. Thus, numerous clinically relevant assessment criteria may be lost. In this study, there was a satisfactory reliability for the constructed scale (a=0.782).

Despite the limitations, the results of this study may serve as a starting point for the further development and validation of assessing the role of the circulating nurse in aseptic practices. The reliability values for the three sub-scales varied, indicating partial premature acceptance of international recommendations. In particular, the sub-scale for the disestablishment of a sterile field may require critical review. Furthermore, a reasonable number of items (and respondents) are needed for future analysis.

Aseptic practice recommendations

The evidence-based aseptic practice recommendations warrant consideration through the actions, skills and concepts of the nursing profession (Niiniluoto, 1993; 1996). As technical norms they provide goals for practical action, express professional expertise and facilitate efficiency in practice. Recommendations cannot always be deduced from general theory alone, but may be supported 'from below'. According to Niiniluoto (1993), the conditions regarding technical norms demand that they hold social relevance in factual situations; they should be at least potentially acceptable among some social groups; they contain evaluative and normative terms; and their relationship to the value system varies from the positivistic ideal. They only become binding among those who accept the premise of their conditional value.

Differences in acceptance of the recommendations in scale testing

In this study, there were no differences in the acceptance of aseptic practice recommendations between project hospitals or between operating theatre and day surgery nurses. This may indicate solid organisational and professional support for the role of circulating nurses in aseptic practice recommendations (Fung-Kee-Fung et al, 2009). Instead, there were differences in the acceptance of recommendations between nurses with a previous college-level education and nurses with a contemporary bachelor-level education.

Nurses with a bachelor's degree reported less acceptance of recommendations for establishing and disestablishing sterile fields than nurses with a college-level education. The difference was not statistically significant for recommendations related to maintaining a sterile field. This may indicate a lack of relevant research or personal knowledge. It may be that acceptance among nurses with a bachelor's degree suffers because they critically reflect on the knowledge base of the recommendations. These results did not support the results of Sessa et al (2011) which indicated that a higher level of knowledge was associated with a higher level of education.

In addition, Sinkowitz-Cochran et al (2012) reported that more knowledge was associated with a high engagement with clinical recommendations. Thus, it may be that the knowledge base around independent clinical decision-making among nurses with a bachelor's degree remains weaker in situations where relevant research does not exist. When maintaining a sterile field, such nurses may also accept clinical reasoning when receiving collegial support from senior nurses who rely on traditional practices.

Initially, interpretation of the lack of differences in recommendation acceptance levels comparing nurses with 5 or more years' general work experience in surgical departments to nurses with less than 5 years' work experience proved difficult. There were differences within recommendations for the establishment of a sterile field between nurses with less than 5 years' and nurses with 5 or more years' work experience in the current setting. Sinkowitz-Cochran et al (2012) found better self-reported hygiene performance and high staff engagement was related to recommendations and hospital leadership. It may be that the development of capabilities in aseptic practices takes longer than general expectation and requires the engagement of the operating theatre culture and staff. The development of expertise may begin with the establishment of a sterile field and extend to expertise in the maintenance and disestablishment of a sterile field. These last two stages may require longer and more extensive work experience, and a greater understanding of aseptic practices than establishing a sterile field.

High acceptance of recommendations among nurses with longer work experience supports this interpretation. There was a higher acceptance of the recommendations for maintaining a sterile field among nurses with 15 or more years' work experience in their current unit than among nurses with less work experience. In addition, acceptance of recommendations for the establishment and disestablishment of a sterile field was higher among nurses with 15 or more years' general work experience than among nurses with less experience. It may be that managing demanding intraoperative aseptic practices like an expert requires time.

An explanation for this may exist in the operating theatre culture. Senior nurses may possess more confidence and assertiveness to create and express solid opinions related to adhering to the recommendations in a multidisciplinary team (Gillespie et al, 2008; Tame, 2013).

Limitations

The results are not generalisable, but should be used in the local development of aseptic practices. The small sample size and the absence of medical staff in the data collection limit the transferability and comparability of the findings to earlier results. Owing to the low overall response rate in 2013, further testing of the acceptance of the recommendations and the scale reliability proved necessary. In early 2000, when development of the recommendations began, the authors

KEY POINTS

- In the absence of analytical tools, few studies exist on intraoperative nursing-related aseptic practices
- In this study there were differences in the acceptance of aseptic practice recommendations for circulating nurses according to education and general and current work experience in operating theatre units
- Continual assessment of the evidence base and comprehensive evaluation represent important components in further developing the tool
- A reasonable number of items covering clinical practice are necessary for assessing the effectiveness and cost-effectiveness of aseptic practices, and a larger response rate is needed to validate the tool in future

applied both factor analysis and principal components analysis aiming to create relevant and valid scales. None of the analyses managed to reduce the variables to logical and practically meaningful factors. Finally, the survey items did not properly cover clinical performance.

Recommendations

By using relevant, valid and reliable tools in the assessment of intraoperative aseptic practices, continuously improving the outcomes of surgery and the capabilities of the operating theatre nurses becomes possible. The evidence-based recommendations serve as technical norms for clinical and educational practices among operating theatre nurses and students (Niiniluoto, 1996). These are key to reducing the number of surgical site infections, improving patient and occupational safety, and decreasing work-related stress (Espin and Lingard, 2001; Aholaakko, 2011; Sinkowitz-Cochran et al, 2012; Tame, 2013).

Sound methodological support is essential in the evidence-based development of intraoperative aseptic practices and multidisciplinary quality management. Testing concepts and the assessment criteria for aseptic practices more carefully to construct stable models for different professional roles and phases of operation are necessary. The results may serve as a starting point for the further development of aseptic practices, which are nursing-specific, and multidisciplinary interventions, and may facilitate improvements to patient safety and operating theatre culture. Future research should focus on studying the aseptic practice-related cultures and outcomes. Similar recommendations and practices should also be developed for demanding facilities such as angiography in the field of radiography.

Conclusions

In the development of assessment criteria for intraoperative aseptic practices, precise and comprehensive scales of both acceptance among clinical professionals and the use of scientific methods are essential. This study demonstrates the reliability of the constructed Aseptic Practices among Circulating Nurses scale, which may serve as a starting point for the further development and validation of assessing the role of the circulating nurse in aseptic practices.

There were statistically significant differences in the acceptance of recommendations for circulating nurses according to education, and general and current work experience in operating theatre units. The work of a circulating nurse includes responsibilities such as aseptic practices facilitating teamwork in a sterile operating field. Traditionally, attention focused on the establishment and maintenance of a sterile field. In future, it is important to develop recommendations covering the entire process, including the disestablishment of a sterile field. To develop evidence-based intraoperative aseptic practices, future research should further study such topics from varying perspectives. BJN

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